SUMMARY REPORT

Peer Review of

(1) Technical Support Document for the Final Round Two Part 503 Standards for the Use or Disposal of Sewage Sludge - Land Application and Surface Disposal

(2) Technical Background Document: Risk Characterization; and

(3) Estimate of Population Exposed to Dioxins from the Land Application of Sewage Sludge and Corresponding Number of Annual Cancer Cases from this Exposure

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Prepared for:

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I. INTRODUCTION

The United States Environmental Protection Agency (EPA), Office of Water is charged with protecting public health and the environment from adverse exposure to chemicals and microbials in water media, such as ambient and drinking waters, waste water/sewage sludge and sediments. In support of this mission the Office of Water/Office of Science and Technology (OST) develops health standards, health criteria, health advisories, and technical guidance documents for water and water-related media. Under this work assignment, documents prepared by OST are to undergo external peer review.

Peer review is an important component of the scientific process. It provides a focused, objective evaluation of a research proposal, publication, risk assessment, health advisory, guidance or other document submitted for review. The criticisms, suggestions and new ideas provided by the peer reviewers ensure objectivity, stimulate creative thought, strengthen the reviewed document and confer scientific credibility on the product. Comprehensive, objective peer review leads to good science and product acceptance within the scientific community.

Under the terms of a Consent Decree, EPA proposed a numerical standard for dioxins and dioxin-like compounds ("dioxins") for land applied sewage sludge on December 23, 1999 at 64 Fed. Reg. 72045-72062 under the 40 CFR Part 503 Standards for the Use or Disposal of Sewage Sludge. At the same time, EPA proposed not to establish standards for dioxin in sewage sludge that is surface disposed or incinerated. The Part 503 Rule is risk-based. Therefore, a comprehensive multi-pathway exposure analysis/risk assessment was performed to determine the concentration of dioxins in sewage sludge that is land applied or surface disposed above which unacceptable risk to public health could occur. A Technical Support Document (TSD), with appendices, described this risk assessment and presented the results for the land application and surface disposal of sewage sludge. As such, the document served as the TSD as well as the technical basis for the proposed numerical standard of 300 ppt TEQ dioxins for the land application of sewage sludge. The results of the risk assessment for the surface disposal of sewage sludge in this TSD also served as the technical basis to support EPA's finding of not proposing a numerical standard for surface-disposed sewage sludge.

EPA has received numerous public comments on the proposal and the TSD. In addition, EPA subjected the TSD to an external peer review. Analysis of the public comments and the peer reviewers' comments produced many useful suggestions for improving the scientific defensibility of the risk assessment and its TSD. EPA subsequently revised the risk assessment and the TSD based on these comments.

Under this work assignment the "*Technical Support Document for the Final Round Two Part 503 Standards for the Use or Disposal of Sewage Sludge - Land Application and Surface Disposal*" was externally reviewed by a panel of three peer reviewers. The three reviewers were Robert J. Fares, Paul S. Price and Curtis C. Travis . A brief description of their background are provided below.

Mr. Robert J. Fares has over 25 years of broad-based experience in the performance of exposure and risk assessments, statistical analysis, field sampling and monitoring, photogrammetric techniques, aquatic bioassay techniques, environmental fate and transport studies of chemical pollutants, acid deposition issues, report writing, literature reviews, data management, and project management. Over 17 years experience in assessing multimedia exposures and associated risks for chemicals in the vicinity of hazardous waste sites, released from point sources (e.g., stacks, outfalls), contaminants released as nonpoint sources (e.g., vertical and lateral movement of pesticides resulting from different agricultural techniques), and chemicals released from commercially available products and furnishings during use by consumers. Over 12 years experience

in the development of experimental designs and computer models, sampling strategies, and statistical analysis of exposure-related data. Because of his familiarity with commercially available stochastic modeling software, currently a Beta tester of software produced by Palisade Corporation (@Risk, BestFit, Risk View, TopRank, and Precision Tree) and Decisioneering, Inc (Crystal Ball). Also very active in the Society for Risk Analysis and served as Chair of the Exposure Assessment Specialty Group during 1994. In addition, reviews papers submitted for inclusion in Risk Analysis, the SRA journal, and serves on the committee responsible for selection of papers for the SRA Annual Meetings.

Mr. Paul S. Price has 26 years experience, and is currently an independent consultant. Mr. Price has published 41 papers in the fields of exposure, risk assessment, dose reconstruction and uncertainty/variability analysis, and has also participated as an invited guest at workshops and given numerous presentations. He also has service as a peer reviewer on federal, state and industry panels, on such topics as PCB carcinogenicity, the use of Monte Carlo techniques, mercury fish consumption intake values, human exposure factors, submitted proposals and residential exposure software. For four years, Mr. Price was Staff Leader for the Benzene Task Force at the American Petroleum Institute to evaluate risks from benzene in petroleum, a position which involved response to federal litigations, policy and strategy formulation, and extensive interaction with industry experts as well as federal and state regulators. Mr. Price served with EPA's Office of Drinking Water and Toxic Substances for eight years as a Chemist, where he was responsible for developing exposure and risk assessments, health advisories and standards, including the fluoride standard, as well as test rules for six glycol ethers and several chlorinated compounds. Mr. Price holds an M.S. in Civil Engineering and a B.A. in Chemistry from the University of Maryland.

Dr. Curtis C. Travis, Vice President (Environmental Risk and Security) for Project Performance Corporation, is responsible for the coordination of risk-related activities of the corporation. During his 33-year career, he has been involved in various aspects of risk assessment and analysis. Dr. Travis has also taught courses in applied and engineering mathematics and computer sciences at the University of Tennessee and Vanderbilt University. Dr. Travis has been Editor-in-Chief of *Risk Analysis: An International Journal*, and is currently on the editorial board of a number of journals, including *Health and Environmental Toxicology*, *Toxicological and Environmental Chemistry, Toxicology and Industrial Health, Journal of Hazardous Materials, Critical Reviews in Environmental Science and Technology*, and *DOE Risk Management Quarterly.* He was president of the International Society of Risk Analysis and has been a fellow of the society since 1992. Dr. Travis has testified to the House Committee on Science, Space and Technology, Subcommittee on Environment on the use of risk analysis for prioritization of environmental spending. He has also addressed the U.S. Senate Committee on Environment and Public Works on the role of risk assessment in Superfund. Dr. Travis has served on the advisory panel for a number of government projects including EPA's Scientific Advisory Panel on FIFRA, EPA Review Panels for Land Application of Pulp and Paper Mill Sludge and Dermal Exposure Assessment, Cancer Risk Assessment Guideline Revision, Biologically Motivated Mathematical Models, and Interim Methods for Development of Inhalation Reference Doses for Systemic Toxicants. Dr. Travis received his Ph.D. in Applied Mathematics from the University of California, Davis, and an M.S. in Biomathematics and a B.S. in Mathematics and Physics, both from California State University, Fresno.

II. CHARGE TO THE PEER REVIEWERS

The peer reviewers were asked to respond to the following questions:

Document No. 1 (The Technical Support Document)

- Is the selection of exposure pathways scientifically reasonable for appropriate characterization of the exposure evaluation as "high end" within the meaning of EPA's *Guidelines for Exposure Assessment*?

- Is the modeling of the accumulation of dioxins in the soil from the land application of biosolids at several land application scenario sites and the accumulation of dioxins in the subsurface environment from the surface disposal of biosolids, including the half life assumptions of applied dioxins as a function of incorporation/burial/stacking depth and application method technically adequate?

- Are the exposure pathway algorithms used to estimate dioxins exposure to the population modeled for each of the identified exposure pathways correct and transparent?

- Are the algorithms used to model the fate of dioxins in biosolids applied to the land and the fate of dioxins in biosolids surface disposed with particular emphasis on bioaccumulation and transport to groundwater algorithms scientifically adequate? (In general, fate pathways include soil-to-air, soil-to-plants, soil-to-plants-to-animals, and subsurface soil to groundwater.)

- Are the selected default values in the exposure pathway algorithms including but not limited to exposure assumptions, fate parameters, bioconcentration factors, decay rates, and all other parameters appropriate for the stochastic modeling runs as well as any deterministic runs performed in the risk assessment?

- Are the calculations for each of the exposure pathway algorithms performed correctly?

If the reviewers disagree with any part of the document or find a weakness in the document, they shall provide explicit guidance on revising the document. They shall provide comments that include an overall general summary on the acceptability and adequacy of the exposure evaluation and risk assessment performed and specific comments as needed.

Document No. 2 (The Risk Characterization)

Based on reference to EPA's *Guidelines for Exposure Assessment*:

- Do you agree with the risk characterization based upon your review of the exposure evaluation and the risk assessment contained in the Technical support Document?

- The reviewers will provide specific language to EPA on their characterization of the risk assessment, e.g., "high end", "bounding", "central tendency", etc.

- If the reviewers disagree with any part of the document or find a weakness in the document, they shall provide explicit guidance on revising the document. They shall provide comments that include an overall general summary on the acceptability and adequacy of the risk characterization performed and specific comments as needed.

Document No. 3 (Estimate of Population Modeled and Annual Cancer Cases from the Modeled Population)

- Are the assumptions that are stated in the estimates reasonable?

- Are the calculations for the estimated population modeled and the annual cancer cases from this population performed correctly?

If the reviewers disagree with any part of the document or find a weakness in the document, they shall provide explicit guidance on revising the document. They shall provide comments that include an overall general summary on the acceptability and adequacy of the estimates of population and annual cancer cases performed and specific comments as needed.

III. GENERAL COMMENTS

Robert J. Fares

Overall, the Technical Background Document was a pleasure to read. Obviously, a lot of thought went into the production of this document. The document generally follows the same format as *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (U.S. EPA, 1998) and has even retained many of the model component names and symbols introduced in that document. The rationale for model development and descriptions of the model components are clear and explicit, and the discussions regarding the development of probability distribution functions (PDF) and exposure point concentration (EPC) estimation was thorough. However, the Technical Background Document had some shortcomings. Specifically, Tables in the document that are supposed to present percentile concentrations estimated using the single sample of dioxins, furans, and PCBs as the fixed congener concentrations in the model were blank. Additionally, the equations in Appendix H are missing their operands. All of the operands in the equations are replaced by vertical rectangles, probably the result of the use of incompatible fonts used in the author's equation editor. Consequently, that limited the evaluation of the equations. Several specific comments follow that point to missing information and minor discrepancies identified throughout the document

Curtis C. Travis

This document describes the risk assessment conducted to determine the total concentrations of polychlorinated-p-dioxins, dibenzofurans, and coplanar polychlorinated biphenyls that can be present in biosolids and remain protective of human health. The risk-based concentration limit is designed to be protective of farmers and their children who apply biosolids to their croplands and pastures and consume home-produced foods.

EPA used both a probabilistic analysis and a deterministic analysis. The probability analysis produces a distribution of risks for each receptor by allowing some of the parameters in the analysis to vary over a range of values. A probabilistic analysis captures the variability in biosolids application practices and the differences in the environmental settings in which biosolids may be land-applied. The purpose of the document was to provide a "high-end" estimate of exposure and cancer risk to an individual farmer and his family from the application of sewage sledge to agriculture land. The estimate of risk is to be used to establish concentration limits for dioxin in sewage sledge that will be applied to agriculture land.

I found the document to be well written, easy to understand, and to provide a comprehensive assessment of the risks posed to humans by the application of sewage sludge on agricultural land. The models employed to evaluate the fate and transport of contaminates provide a realistic assessment of the probable concentrations of pollutants at points of human exposure. The models used in this assessment are reasonable and are similar to those used in other EPA assessments and, for the most part, are accepted as state-of-the-art by the scientific community. The atmospheric transport model used is an EPA recommended model that has had widespread application is other risk assessment. The model developed to characterize uptake of contaminants into the food chain (the dominate exposure pathway) is state-of-the-art and has also been used in previous assessments. It is my belief that these methodologies provide an adequate basis for a national level assessment The exposure pathways selected for analysis represent pathways most likely to result in significant human exposure and thus provide a reasonable worse case analysis. The parameters used in the analysis are appropriate. I thus believe that the current document represents a complete and comprehensive

analysis of reasonably anticipated high-end exposures and risk from the land application of dioxins and related compounds in biosolids in an agricultural setting.

Climate Regions

The document does not tell how the climate regions were selected. Were they selected based on fairly uniform soil characteristics or meteorological data within a region, or both? In predicting soil concentrations, which is more important, the soil temperature and amount of rainfall or the soil characteristics? The answer to this question will determine how one would want to select the 41 climate regions.

In performing the analysis, one of the 41 climate regions is picked at random and modeling is done using the characteristics of that region. The process is repeated 3,000 times. This approach gives equal weight to all climate regions in the U.S. However, not all climate regions have the same number of farms and, consequently, the same number of exposed farm families. The document should discuss this issue and explain why it is not a problem for the current assessment. I believe it is not a problem in estimating the "high-end" individual exposure, but it will produce an inaccuracy in estimating the total population exposure. Nevertheless, some discussion of this issue is needed.

Linearity

In calculating the Risk-Based Waste Concentrations (page 7-10), the text states, "This scaling approach is allowable since all of the modeling results in the analysis were linear with respect to the initial biosolids concentration." However, the document seems to indicate on page 5-17, paragraph 2, that there is a nonlinear relationship between farm size and air concentrations. Page 5-24, paragraph 1 gives a hint that soil concentrations in cold climates may be nonlinear with farm size. This discrepancy needs to be explained.

Nursing Infant

The analysis allows for exposure to an infant via the ingestion of breast milk. The mother is assumed to live on the farm and ingest contaminated food and receive exposure through other pathways, with some of the contamination stored in the fat of her breast milk. The infant is then exposed during nursing. The exposure duration for the mothers averages 18.75 years (Table J-14, page J-27). It can be assumed that the concentration of dioxin in breast milk of the mother will increase throughout this exposure. The document does not state at what time during the mother's exposure the infant begins nursing. Is it assumed that nursing begins at the end of the mother's exposure?

Intake Factors

In the section defining the distributions on intake parameters (section 6.2.1, pages 6-7 through 6-29), the document does not use a consistent definition of central tendency and high-end exposures. For example, in tables 6-4 and 6-5, the central tendency for the child is less than the P50 value, while the central tendency for the adult is slightly greater than the P50 value. The high-end intake for the child is less than the P90 value, while the high-end for the adult is greater than the P90 value. Similar problems occur with the other intake parameters in this section. The document needs to define how it is selecting high-end values for children and adults.

Frequently, all the consumption distributions but one are lognormal. It might be better to just use a lognormal distribution for all exposure distributions. This would lead to consistency and simplicity in exposition.

The percentage of consumption that is homegrown sometimes seems too large. For example, it hard to believe that the average farm household produces 32.8 percent of their fruit intake or 25.4% or their dairy product intake or that adult fishers catch 32.5% of their total fish intake (and 64% of T4 fish) in streams near

their farms. The document needs to explain that these estimates are only being used to insure that the analysis is a high-end estimate and that it is unlikely that any single family would be exposed to all of these pathways simultaneously.

Groundwater

The document talks about estimating leaching of contaminant from the agricultural fields to groundwater. However, the document never says how important this pathway is, nor does it give a risk estimate for this pathway of exposure in Chapter 7. The document should say that this pathway is only included in the analysis to insure realistic calculation of soil concentrations, but that exposure to ingestion of groundwater is not a pathway of exposure considered in this document. The document might also want to say (if it is true) that dioxin is relatively immobile in soil and does not reach groundwater in sufficient concentration to pose a risk to humans.

Exposition

The document needs to add more information concerning the results of the analysis. How do soil concentrations behave over time, that is, what is the factor of buildup over the lifetime of application? What are the major loss pathways for soil: leaching, volatilization, and degradation? How do buffer zone soil concentrations compare with crop and pasture land? What is the relative importance of air deposition and surface runoff in buffer zone soil concentrations? What are the major food chain pathways for exposure and what is their relative contribution? What are the major pathways of exposure to the farmer? What is the percentage contribution of air, soil ingestion, terrestrial food, and fish to exposure? What is the percentage contribution of the various pathways to total risk? Table 7-12 provides some perspective but it is not sufficient.

Sensitivity Analysis

The introduction and overall description of the sensitivity analysis needs improvement. The description on pages 8-4 through 8-5 and pages K-3 through K-4 will not be understandable by the average technically trained reader.

Paul S. Price

I found this review difficult to perform. The Document 1 was incomplete. Tables were blank and certain sections were labeled as "under revision". An even greater problem is that Documents 1 and 2 are unclear as to the goals of the risk assessment and the role that the risk assessment would play in setting biosolid standards. Documents 1 and 2 should be revised to include a clear description of the regulatory process that will be used to set the standards for the compounds and the role that the risk assessment will play in the process.

The major questions that should be address in the revisions include the following:

- What is the purpose of the Monte Carlo analysis of the NSSS data? Was the analysis meant to be used a criteria for deciding the need for standards? The findings in Section 7.3 appear to provide a reasonable justification for no regulation of the compounds. (No risks exceeded 10-5 at either the 90th or the 95th percentiles). If this was not the purpose why was the analysis performed.

- Does EPA intend to set standards for the compounds based on an aggregate exposure assessment (as implied by Figures 3.1 and 6.1 and the text in Section 7.1.2) or based on the highest single dose from one of the multiple routes of exposure (as implied by Table 7-12)?[1]

  – If EPA is not going to perform an aggregate assessment why base the exposure on such a hypothetical "conceptual site layout"? It would be more appropriate to assess exposures cattle ranches, poultry farms, and vegetable farms separately and develop separate and more representative fate/transport/exposure scenarios for each type of farm.

  – If EPA was going to perform an aggregate assessment then additional documentation will need to be added to show how the total dose in a modeled individual will be characterized. Relevant guidance on 0performing aggregate exposures has been developed by EPA's Office of Pesticides Programs and can be found at: http://www.epa.gov/pesticides/cumulative/Cum_Risk_AssessmentDTM.htm#Aggregate. A key issue that will need to be considered is the correlation between the intake rates of foods (will high intake of beef suppress intake of dairy and poultry?)

- How will EPA use this assessment to set standards? The current text and terms such as scaling factors, SBC, fixed concentration sample, and Risk Limiting Concentrations are unclear.

  – The text in 7.2 suggests that EPA will assume that all biosolids will look like a "known biosolids sample". This implies that all biosolids will be assumed to have the same proportions of compounds as the "known biosolids sample". This is clearly untrue. As the NSSS demonstrates the concentrations of specific compounds vary from one sludge to another.

    EPA states in Document 2 that beef consumption is responsible for most risk. If this is true, then the risks offered by a biosolids will be a function of the TEQ's for each of the compounds in combination with the relative potential of compound to reach receptors through the beef consumption pathway. See the addition discussion on this point below.

  – While Section 7 is being modified, it is disconcerting that the beef pathway risks predicted for the "known biosolids sample" (Table 7-7) are 20 time higher then the results from the NSSS Monte Carlo analysis (Table 7-18). EPA needs to provide an explanation for this difference.

The high-end population needs to be better defined. Specifically the population needs to be defined in terms of actual demographics and farming practices. Once this is done then EPA should relate the population to "conceptual site layout". The layout and the derived exposure scenarios are not the high-end population as stated on Document 2 (Page 3-Paragraph 2), they are a simulation or "model" of the high-end population that needs justification.

The Monte Carlo model is clearly an essential portion of the regulation since it is the means of generating the 90th percentile dose, which appears to be the point of departure for the proposed regulations. Unfortunately, the use of the conceptual site layout is a problem for the Monte Carlo analysis. Because the

[1] While not asked, I strongly suggest that EPA should regulate based on aggregate exposure since this is the most protective of public health.

layout is so contrived and unrepresentative it is difficult to talk about how it "varies". It is valid to talk about data on regional variation in farm size, soil types, and meteorological data for cattle ranches, watersheds, dairy farms, and truck farms and whether the distributions in inter farm variations in these properties are accurate. However, a conceptual layout that that is a composite of all the land uses cannot be evaluated.

What is the purpose of the Monte Carlo assessment? If the goal was to look at variation in the subpopulations (farmer adult, child, infant, and fisher) by pathway the model has the following problems:

a. Did not consider variation of soil types or farm sizes within the 41 climatic regions.
b. The 41 regions should be weighted according to the number of farms that will be used for biosolids disposal. For example, Billings would be given a very low weight since the farms are large and the populations (and thus sludge generation) will be small. LA would be given a high weight for the small farm size and large population size
c. The use of residential mobility as a measure of duration only works if moving from on farm means a cessation of exposure. A farmer may move to another farm practicing biosolids disposal. This needs to be discussed.
d. Children growing up on farm may become farmers. This needs to be discussed.

The discussion of the Monte Carlo model is incomplete and scattered.

a. The model is apparently written from scratch but no description of the model language used, platform, or code is provided. The recent guidance for Monte Carlo (cited in document 1) provides guidance on the minimum information that should be included in a Monte Carlo analysis.
b. The design of the model should be provided (a flowchart is essential).
c. The relationship of the model to the soil, air dispersion, watershed and other fate and transport models should be described (were these models run inside of the Monte Carlo Model or were inputs and outputs of these models used to create a response surface that was used in the Monte Carlo Model).
d. The description of the Monte Carlo should differentiate between the model that will be used to set the standards and the NSSS analysis.

EPA seems to have gone out of its way to fit empirical data to parametric distributions. The reason for this is unclear. Entering empirical data would have been easier and would not have introduced the uncertainty in parametric curve fitting.

Finally, the Monte Carlo model assumes that exposures to one individual will remain constant over time. That the dose to each simulated individual will be constant for the entire duration of his or her exposures. This means that each day the person will have the same beef intake and that all sludge applied to a farm will be constant in composition. These assumptions have the potential to bias upper the estimates of dose at the upper end of the distribution (Price et al. 1996).

IV. RESPONSE TO CHARGE

1. Is the selection of exposure pathways scientifically reasonable for appropriate characterization of the exposure evaluation as "high end" within the meaning of EPA's Guidelines for Exposure Assessment?

Robert J. Fares

The exposure pathways presented in the Technical Support Document incorporate data to account for conditions at geographic locations throughout the United States that result in higher concentrations of dioxins, furans, and PCBs in air, soil, and sediment, and increased transfer to vegetation, farm animals, and fish. Inclusion of these data in the assessment ensured that high end exposure could be characterized in addition to central tendency estimates for farm families and recreational fishers.

Curtis C. Travis

The exposure pathways considered in the document are reasonable and appropriate for a "high-end" assessment. The exposure pathways selected represent pathways most likely to result in significant human exposure and thus provide a reasonable worse case analysis. The parameters used in the analysis are appropriate.

Paul S. Price

The pathways were appropriate for the analysis of a high-end population for exposure to chemicals in biosolids. It is not clear how the EPA Exposure Guidelines are relevant.

2. ***Is the modeling of the accumulation of dioxins in the soils from the land application of biosolids at several land application scenario sites and the accumulation of dioxins in the subsurface environment from the surface disposal of biosolids, including the half life assumptions of applied dioxins as a function of incorporation/burial/stacking depth and application method technically adequate?***

Robert J. Fares

The half-life assumptions and modeling approach to depict accumulation of dioxins in soils resulting from land application of biosolids appears to be adequate.

Curtis C. Travis

The modeling of the accumulation of dioxins in the soil appears to be reasonable and adequate for a national level assessment. All of the important processes effecting the fate and transport of dioxin in soil are considered. The algorithms used to account for the different fate and transport processes are appropriate and the parameters used in the algorithms seem reasonable. The half-life assumptions seem appropriate. Thus, I believe that the procedures followed in the document give a reasonable estimate of "high-end" concentrations of dioxin in soil and other media at likely points of exposure.

Paul S. Price

Soil modeling is outside of my area of expertise. I did not review the models.

3. *Are the exposure pathway algorithms used to estimate dioxins exposure to the population modeled for each of the identified exposure pathways correct and transparent?*

Robert J. Fares

The exposure pathway algorithms described in the body of the Technical Support Document appear to be correct, and the discussions regarding the equations (including justification for specific assumptions) make them quite transparent. However, the equations in Appendix H are missing their operands. All of the operands in the equations are replaced by vertical rectangles, probably the result of the use of incompatible fonts used in the author's equation editor. Consequently, that limited the transparency of the equations and made it difficult to evaluate the correctness of certain equations.

Curtis C. Travis

The exposure pathway algorithms used to evaluate exposure from the selected exposure pathway are correct and appropriate. The algorithms used are similar to those used in other EPA assessments and are consistent with EPA guidelines.

Paul S. Price

The equations were transparent. EPA/RTI should be congratulated on making the system of equations open for review. I did not exhaustively review all equations. See specific comments below for suggestions on certain equations. The paper and electronic copies of the equations were difficult to review since many of the symbols did not convert to the .pdf format correctly.

4. ***Are the algorithms used to model the fate of dioxins in biosolids applied to the land and the fate of dioxins in biosolids surface disposed with particular emphasis on bioaccumulation and transport to groundwater algorithms scientifically adequate? (In general, fate pathways include soil-to-air, soil-to-plants, soil-to-plants-to-animals, and subsurface soil to groundwater.)***

Robert J. Fares

As indicated in the General Comments, the Technical Support Document generally follows the same format as Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions (U.S. EPA, 1998) and has even retained many of the model component names and symbols introduced in that document. In some cases, the algorithms used to model the fate of dioxins differ from those employed in the former document, but still appear to be scientifically adequate. One discrepancy noticed by this reviewer concerns the estimation of diffusivity in water. The authors used an equation that relies only on the molecular weight of a chemical to calculate diffusivity in water. Diffusivity is affected by many things including, temperature, atmospheric pressure, viscosity of water, and atomic and structural differences. Why didn't the authors consider the procedure described by Lyman et al. (1990) since they apparently used the approach to calculate diffusivity in air?

Curtis C. Travis

The algorithms used in this document to model the fate of dioxins in soil, air, food and water are appropriate for a national level analysis. They represent state-of-the-art models for the evaluation of the multimedia partitioning and fate of contaminates in a national level assessment. The soil-to-plants and the soil-to-plants-to-animals algorithms are based on the best of current knowledge and include all of the most important pathways for the incorporation of contaminates into the terrestrial food chain. The parameters used in these food chain algorithms are reasonable and appropriate. The algorithms used to evaluate transfer from soil to air and groundwater are reasonable and appropriate for the type of analysis performed.

Paul S. Price

The pathways looked appropriate. The appropriateness of the specific models used is outside of my area of expertise.

5. ***Are the selected default values in the exposure pathway algorithms including but not limited to exposure assumptions, fate parameters, bioconcentration factors, decay rates, and all other parameters appropriate for the stochastic modeling runs as well as any deterministic runs performed in the risk assessment?***

Robert J. Fares

Overall, the selected default values in the exposure pathway algorithms appear to be appropriate. However, this reviewer was curious regarding the maximum value assumed for fish ingestion. Throughout the document, the authors state that a third order stream was selected because it represents the smallest water body that would routinely support recreational fishing of consumable fish. But the authors used the ingestion rate for subsistence fishers to account for high end exposure. Did the authors consider using a high percentile value for recreational fishers? Also, in Appendix C, the authors stated that the assumption for "veg" (the fraction of vegetative cover for the inactive source) was based on professional judgment, yet they assigned a Normal distribution for use in the stochastic model. That implies that enough is known about the data that professional judgement would not be necessary. This needs to be clarified in the document. There is also some confusion in Section 6 in Tables that contain information on multiple distribution types. In those Tables (6-4, 6-6, 6-8, 6-10, and 6-24), the parameters of Gamma and Weibull distributions are erroneously labeled "Pop-Estd Mean" and "Pop-Estd Sdev". Those values actually represent "Pop-Estd Shape" and "Pop-Estd Scale" values. A footnote is needed in those Tables to make that clarification.

This reviewer had some questions regarding the analytical approach used by the authors to develop probability distribution functions (PDFs) for the stochastic modeling effort. Use of maximum likelihood estimation is appropriate to fit parametric models to data. This reviewer questions the use of chi-square to assess goodness of fit. One of the weaknesses of the chi-square test is that different conclusions can be drawn from the same data depending upon how many intervals are specified. The Kolmogorov-Smirnov test, on the other hand, is not interval-dependent, thereby making it more powerful than the chi-square test. However, it is not very effective in detecting discrepancies in the tails of data. The Anderson-Darling test also is not interval-dependent, and places more emphasis on the tail values. This approach is more robust than either chi-square or Kolmogorov-Smirnov. At minimum, the authors need to report the associated p-values of the chi-square test results.

Curtis C. Travis

The default values used in this assessment appear to be reasonable and appropriate and follow EPA guidance on selection of parameters for a "high-end" assessment. While I do not agree with every default parameter selected, the default parameters selected agree with those in other recent EPA documents and have previously undergone peer review. I do agree that the parameters selected are likely to give an over estimate of individual exposure and risk. The stochastic analysis appears to be performed corrected and should provide an reasonable "high-end" characterization of the individual risk resulting form the use of biosolids on agricultural land.

Paul S. Price

In general, the values appeared to be reasonable. See specific comments on default values and distributions given below.

6. *Are the calculations for each of the exposure pathway algorithms performed correctly?*

Robert J. Fares

This charge cannot be answered fully until Appendix H is corrected so that the equation operands are visible. This inadequacy was reported on December 7, but no one at EPA was available to distribute the corrected Appendix H to reviewers. Also, with regard to risks, the authors inserted a comment following Section 7.1.2 that Sections 7.1.3 through 7.2 have not been revised to reflect new sample data.

Curtis C. Travis

The calculations in the document appear to have been performed correctly.

Paul S. Price

This question is not appropriate. I do not believe that external peer review should include performing a QA/QC of Agency's algebra. However, in my limited review I did not identify any math errors in the deterministic analysis. Finally, such a determination is not possible for the Monte Carlo analysis.

V. SPECIFIC COMMENTS

Curtis C. Travis
Page 1-1; Paragraph 3
I think that in addition to the current overview of the purpose of the document, EPA should say that this assessment will look at risk from a national perspective and attempt to provide a characterization of the high-end of the nationwide probability distribution of individual risks resulting from application of biosolids to agricultural fields.

Paul S. Price
Chapter 2.0
EPA should have investigated whether risks from PCBs would be better regulated based on PCB specific cancer potencies rather than TCDD-related potencies.

Curtis C. Travis
Page 2-1; Paragraph 1; Last Sentence
It is not clear what the document means by the statement, "The cancer slope factors for all of the dioxin, furan, and polychlorinated biphenyl congeners considered in this analysis are based on the toxicity of the most highly characterized congener, 2,3,7,8-TCDD." Does this mean the slope factor for 2,3,7,8-TCDD was used for all other compounds or that a toxic equivalent method was used that based the cancer potency of the other compounds on that of TCDD?

Curtis C. Travis
Page 2-1; Paragraph 2
The document says, "The cancer slope factor for 2,3,7,8-TCDD used by EPA in this and other recent assessments is 1.56x105 (mg/kg/day)-1." This risk factor differs from EPA's more recent cancer slope factor for TCDD in U.S. EPA 2000.

Curtis C. Travis
Page 2-2; Section 2.1.1
This section is well written and clear.

Curtis C. Travis
Page 2-4; Paragraph 2
The document says, "…all provide support for an association between exposure to dioxin and related compounds and increased cancer mortality." This statement seems overly strong. There is no doubt that TCDD is an animal carcinogen. However, EPA concluded in EPA 2000 that the epidemiological evidence for TCDD carcinogenicity is inconclusive.

Curtis C. Travis
Page 2-6; Paragraph 2
The document says, " 2,3,7,8 TCDD …is described as potentially multisite carcinogens in the more highly exposed human populations…" As this document points out on page 2-1, paragraph 1, "EPA characterizes 2,3,7,8 TCDD as a "human carcinogen"", Thus why do you say it is "potentially" a multisite carcinogen?

Curtis C. Travis
Page 2-6, Paragraph 3
I am in agreement with this paragraph.

Curtis C. Travis
Page 2-6; Paragraph 4
The document says, "TCDD is characterized as a multistage carcinogen because it increases the incidence of tumors at sites distant from treatment sites and at does well below maximum tolerated dose." What does increasing the incidence of tumors at sites distant from treatment sites and at does well below maximum tolerated dose have to do with showing TCDD is a multistage carcinogen?

Curtis C. Travis
Page 2-6; Paragraph 4
The text says, " The strength of this association is understood by the fact …" This sentence is unclear. The strength of what association? How do positive bioassays help in the understanding of an association? They may strengthen an association, but they do not increase understanding of the association.

Curtis C. Travis
Page 2-7
I agree with the statements on page 2-7.

Robert J. Fares
Page 2-9; Table 2-2
Table 2-2 should be presented after it is introduced in the body of text.

Curtis C. Travis
Page 2-10; Paragraph 2
This clarifies the use of the risk factor on page 2-1.

Curtis C. Travis
Page 3-1; Paragraph 4
I like the approach of subdividing the United States into 41 climate regions assumed to be uniform in climate. At this point the document does not tell how the regions were elected. I assume that explanation will come later.

Paul S. Price
Chapter 3.0; Section 3.1.3.1
Why is EPA assuming that a single farm will occur down wind of a watershed? EPA should investigate the impact of having air releases from multiple farms affect a single regional watershed.

Paul S. Price
Chapter 3.0
Define what is meant by a third order stream since this is the first time the term is used.

Paul S. Price
Section 3.1.3.2
The proposed approach to modeling inter-farm variation in size, meteorological data, and soil type is to develop typical values for 41 meteorological regions. EPA should discuss why these 41 values are a reasonable model of inter-farm variation. This demonstration should address:

The soil and climate characteristics that may differ for pasture (lower quality soil or less rainfall) and crop land (better soils more rain).

The number of farms in different portions of the US that use biosolids (this will be proportional to the amount of biosolids produced and the fraction that is land disposed, and

farm size.

EPA is to be commended for keeping the meteorological data, soil data, and farm size data linked on a regional basis. This will avoid errors from mixing data from different regions.

Curtis C. Travis
Page 3-5; Section 3.1.5.1
Since a lactating wife was mentioned on page 3-2, I assume that a lactating mother is also assumed to be a human receptor.

Curtis C. Travis
Page 3-5 Section 3.1.5.2
The exposure pathways considered are appropriate.

Curtis C. Travis
Page 3-6; Section 3.1.7
The method presented for calculating protective biosolids concentrations seems reasonable.

Paul S. Price
Section 3.1.7
Risks will not be linearly related to the TEQ of a biosolids. Consider the following example. Sludge A has 1 ppm of 2,3,7,8 TCDD. Sludge B has 10 ppm of 2,3,7,8-TCDF. Both have the same TEQ (1 ppm). However, the 2,3,7,8-TCDD has a beef bioaccumulation factor of 5.76 and 2,3,7,8 TCDF has a beef bioaccumulation factor of 1.25 (more than 4 fold lower). Assuming that the two compounds behave similarly in soil and the resulting soil concentrations are proportional to the levels in the sludges, then the exposure (on a TEQ basis) through the beef pathway will be four fold lower for B than A.

This example is hypothetical. It may be the case that, the biosolids are sufficiently similar that the variation in chemical concentrations and its effect on fate/transport/ bioaccumulation/exposure is sufficiently small that it can be ignored. However, EPA needs to investigate this issue and develop data that justifies the claim that TEQs are linearly related to risk.

Curtis C. Travis
Page 3-6; Section 3.2
The text says, "The primary methodology for this assessment was to estimate risk using a probabilistic approach." First, I think this sentence should say, the primary objective for this assessment was to estimate risk using a probabilistic approach. Second, the section should be clearer as to what the probability distribution is describing. For example, that it is the probability distribution of the risk from exposure to TCDD in sewage sledge to an individual (or certain receptor type) drawn at random from the United States.

Curtis C. Travis
Page 3-6; Section 3.2.1
A Monte Carlo simulation is the correct manor of performing this analysis.

Curtis C. Travis
Page 3-7; Paragraph 2
The text says, "…locations were first selected at random with equal probability of occurrence based on the 41 climate regions." It would seem that if one really wanted to obtain a probability distribution of risk representative of the United States, one would have to select the locations using a population weighted probability. The 41 geographic regions have different total populations. If one wants the final individual risk distributions to be representative of the United States, these different populations totals need to be taken into account. Using a population weighting to select the geographic location will also provide a population weighting on the climate and soil parameters.

Curtis C. Travis
Page 3-7; Section 3.2.2
The method outlined in this section seems reasonable.

Paul S. Price
Section 3.2.2
How were the values selected for soil type/farm size/and met data selected for the central tendency and the high-end analyses performed in the deterministic analyses? Were the values kept linked? EPA should describe the process.

Curtis C. Travis
Page 4-1; Section 4.2
It is not clear what the document means by "Biosolids in this risk assessment were assumed to be characterized by a single distribution of physical and chemical characteristics." What does the phrase "single distribution" mean?

Curtis C. Travis
Page 4-1; Section 4.2
This section should have a sentence that explains how one combines these parameters with those of agricultural soil where the biosolids are applied to soil.

Robert J. Fares
Page 4-2; Table 4-1
Insert Source for fraction organic carbon.

Curtis C. Travis
Page 4-2; Table 4-1
A single number is used to characterize the fraction of organic carbon. One would think that this is a sensitive parameter and should be characterized by a distribution.

Robert J. Fares
Page 4-2; Paragraph 4; Line 5
The authors indicated that the strata were given weights of 0.0035,0.03902,0.23027, or 0.71921. Shouldn't the sum of these values equal 1.00000?

Curtis C. Travis
Page 4-2; Section 4.2.1
This section is clear. Two important assumptions are made in this section: 1) the frequency with which a facility is selected is weighted according to the quantity of biosolids produced by the facility, and 2) when congener concentrations are below the minimum detection limit, a concentration equal to half of the detection limit is assumed. I agree with both of these approaches.

Paul S. Price
Section 4.2.1
The Monte Carlo analysis implicitly assumes that the composition of the chemicals in the biosolids applied to a farm will remain constant over the 40-year period. At a minimum EPA should determine if this assumption is valid and if not what is the impact on the risk assessment. This also has implications for the enforcement of the final standards. If the levels in biosolids vary then the final standards may be best-evaluated using composite sample that reflect long-term averages in contaminate levels.

Curtis C. Travis
Page 4-3; Section 4.2.2; Last Sentence
The document says, " Application rates for biosolids were not associated with location in this analysis." This sentence could be made clearer. You might say, For this analysis, application rates were assumed to be uniform across the nation.

Curtis C. Travis
Page 4-4; Section 4.3.2
The document says, "The boundaries of the climate regions used in this analysis were drawn to circumscribe areas that could be represented by a single set of climate data." The document is not clear as to what climate data were important in selecting the 41 climate regions. Was rainfall the only variable used, or were temperature and wind speed also used?

Paul S. Price
Section 4.3.2
As discussed above, the regions should not be weighted equally.

Paul S. Price
Section 4.3.2.3
Shouldn't the characteristics of the soils be modified to reflect the impact of prior sludge applications? It does not appear that this is taken into consideration. At a minimum, give an explanation why it is not important.

Curtis C. Travis
Page 4-5; Table 4-2
It is not clear how farm size is used in this document. On page 4-4, paragraph 2, the document says the agricultural field area of the general site layout, as shown in Figure 3-1, is assumed to be the median area for farms in each climate region. But how does farm size affect the analysis? I assume that it effects the environmental partitioning (and maybe the total source term), but if so, the document should have a sentence indicating this so that the reader has a better idea of what is going on.

Curtis C. Travis
Page 4-6; Paragraph 1
How were the meteorological station selected to represent each of the 41 climate regions? Since on page 4-7, land use percentage around each meteorological station is used to estimate meteorological parameters, how the meteorological stations were selected might affect the analysis.

Curtis C. Travis
Page 4-6; Paragraph 1
The document says, "Each climate region was equally weighted in the probability analysis." I'm not sure that this is the correct to perform the analysis. One might think the climate regions with greater population would be weighted more heavily. Why is this not the case?

Curtis C. Travis
Page 4-6; Section 4.3.2.1
How were hourly surface meteorological data used in the Monte Carlo analysis?

Curtis C. Travis
Page 4-7; Paragraph 1
The document says, "…the station was discarded and another nearby station was selected to represent the site." The replacement station does not have to be a nearby station, just another station in the same region.

Curtis C. Travis
Page 4-7; Last Paragraph
Since land use information is important, I would think EPA would find the land use information around each meteorological station in a climate region and then average them to obtain a land use profile for each climate region. It appears from the description that EPA selected a single meteorological station within a climate region as the basis for determining land use patterns. If the meteorological station selected was near an urban area, the land use patterns might not be representative of rural areas.

Curtis C. Travis
Page 4-12; Section 4.3.2.3
It is not clear if probability distributions or point estimates were used for the soil types within a climate region.

Curtis C. Travis
Page 4-12; Section 4.3.2.3
The document says, "Soil properties are listed by data source and model in Appendix E." This sentence is unclear. First, appendix E does not contain soil types. Second, what does listed by model mean? There is no mention of models in appendix E.

Curtis C. Travis
Page 4-16; Table 4-9
It is not clear what the titles of the columns mean. For example, what do Ksat, WCS, RHOB, and SMb mean?

Curtis C. Travis
Page 4-18; Paragraph 2; First Bullet
The text says, "Table 4-9 presents the mean value for field capacity (SMFC) by hydrologic soil group…" The symbol SMFC does not appear in Table 4-9
Curtis C. Travis

Page 4-18; Paragraph 2; Second Bullet
The text says, "Table 4-9 lists the mean value for wilting point by …" The symbol SMWP does not appear in Table 4-9.

Robert J. Fares
Page 4-19; Paragraph 3; Line 7
What are the units of the conversion factor 174?

Curtis C. Travis
Page 4-20; Paragraph 2
There is a typo in this paragraph. The text says, Censue of Agriculture (U.S. DOC, 1989, 1996). It should say, Census of Agriculture.

Curtis C. Travis
Page 5-2; Section 5.1.1.1
The text says, "The sheet-flow-only restriction is based on the assumption that any area downstream …" The document is not clear as to what the sheet-flow-only restriction is. Does that mean that the only way pollution enters downslope areas is through overland flow?

Curtis C. Travis
Page 5-4; Section 5.1.1.2
I agree with the first three assumptions used in the LAU model. They are standard and reasonable. With regard to the last two assumptions, it is not clear if the first-order loss rates from soils are used only as a source term to air or if they also result in loss of contaminate from soil. The forth bullet says it is possible for immobile constituents to build up in the soil. However, it is not clear if this is because the application rate is greater than the first-order soil loss rate or if it is because if the first-order loss rate is not used to deplete soils of their contaminates.

Curtis C. Travis
Page 5-5; Equation 5-1
This equation answers my immediately preceding question, but I still think you should make the point clear in the text on page 5-4.

Curtis C. Travis
Page 5-5 and 5-6
The explanation of how equation 5-1 is solved is clear and seems to be a reasonable approach. The use of a 200-year time limit is a risk management assumption, but seems reasonable. I certainly would not use a longer time period without good justification because of the increase in uncertainly that comes when modeling over long time periods.

Curtis C. Travis
Page 5-7; Equation 5-3 and 5-4
These are standard equations and are appropriate. The implication that the soil column sportive capacity does not become exhausted is important to point out. However, for dioxins, which will be immobile in the soil and thus build up, this may lead to unrealistic conditions in the soil. Do soil concentrations of dioxin stay low enough in soil over time that the linear assumption (equation 5-3) seems reasonable?

Curtis C. Travis

Page 5-7; Third to last Bullet
The text says, "The total chemical flux is the sum of the vapor flux and the flux of the dissolved solute." What about chemical loss from soil due to wind erosion, vehicular activity, and tilling operations?

Curtis C. Travis
Page 5-7; Bullets
All of these assumptions seem reasonable and standard.

Curtis C. Travis
Page 5-9; Paragraph 1
Pointing out that no enrichment for small particles is assumed is good. This assumption seems reasonable.

Curtis C. Travis
Page 5-9; Paragraph 2
The document says that validation was not carried out because the sites modeled are hypothetical. This does not seem like a valid reason. The only thing hypothetical about these sites are the exposure scenarios. The soil properties, meteorology, hydrology, etc are real. Thus, validation could theoretically be carried out. However, the real reason validation cannot be done is that you need real date from real sites to do validation. Such data are not available for all the components of this modeling effort. However, some components of the modeling approach have undergone validation, for example, the atmospheric component.

Curtis C. Travis
Page 5-10; Paragraph 1
It would be interesting if the document gave the primary soil loss mechanism leading to the observed TCDD half-life in soil. I assume that it is volatilization, as opposed to soil leaching or particle loss from the soil surface.

Curtis C. Travis
Page 5-10; Table 5-1
These soil-loss half-times indicate that the 200 years used in the simulations (page 5-6, paragraph 2) is more than adequate. What is the source of the variability in half times? Is it the variability in soil and meteorology conditions across the U.S.?

Curtis C. Travis
Page 5-11; Paragraph 1
The document says, "These observed half-times seem to corroborate the range of half-lives resulting from the source model funs, thereby affording a measure of credibility to the modeled results." This exercise, which I highly indorse, says little about the validity of the individual model components. It does tell you that you have the rate coefficient for the dominant loss term from soil about right. That gives you some confidence that estimated soil concentrations are not too low. While this exercise in calculating TCDD half time in soils does not validate the models, it is still highly informative and I am pleased that it was included. It is a good reality check to see if the model is running in a reasonable way. The modelers are to be congratulated for including it. It would be nice to include other calculations, like partitioning percentage of TCDD in soil verses soil water and compare that with field data.

Curtis C. Travis
Page 5-12; Section 5.2.1.1
I agree with the use of the ISCST3 model for this exercise. It is a standard EPA model that has been used extensively in regulatory applications. It has received widespread review during previous applications.

Curtis C. Travis
Page 5-13; Paragraph 2
This is a good description of the ISCST3 model. The paragraph says, "…vertically according to a Gaussian distribution, which is similar to a normal distribution." You might want to say, "according to a Gaussian distribution, which is another name for a normal distribution."

Curtis C. Travis
Page 5-13; Section 5.2.1.2; Paragraph 2
The use of unit values for air concentrations and deposition rates is standard and appropriate.

Curtis C. Travis
Page 5-14; Paragraph 3
Pointing out that depletion of vapors from the plume was not considered is appropriate. This should not have a large effect of modeled air concentrations.

Curtis C. Travis
Page 5-15
The descriptions given on this page are clear and appropriate.

Curtis C. Travis
Page 5-16
TOXICS vs. Regulatory Mode. It is appropriate to use the TOXICS mode in this assessment.

Curtis C. Travis
Page 5-17; Section 5.2.1.4
Why would air concentration depend nonlinearly on source area size? You say on page 5-13 that you use unit air concentrations based on unit emission rates. Thus, you assume a linear relationship between air concentration and emission rate. Thus, I can assume that the relationship between farm size and emission rate is nonlinear. Why is this?

Robert J. Fares
5-18; Table 5-3
Concentrations are missing.

Curtis C. Travis
Page 5-18; Table 5-3
There are no numbers in this table.

Curtis C. Travis
Page 5-18; Table 5-4
How do these air concentrations compare to background air concentrations of TCDD? What percentage of TCDD in air is attached to particulates and what percentage is in vapor form? How does this compare to ambient measurements for TCDD percentages in air? This point is important because it influences how much dioxin is taken up in vegetation through air-to-plant transfer. Presenting these ratios provides another check on the validity of the modeling results.

Curtis C. Travis
Page 5-18; last Bullet
What is the most important meteorological parameter, temperature? The examples given on page 5-19 of the highest 1 percent air concentration seem to support this view.

Curtis C. Travis
Page 5-19; Section 5.2.2
This section is clear.

Robert J. Fares
Page 5-22; Table 5-5
Concentrations are missing.

Curtis C. Travis
Page 5-22; Table 5-5
There are no numbers in this table.

Paul S. Price
Tables 5-5, 5-8, 5-10, 5-12, 5-14, 5-16, and 5-18
The tables are empty.

Curtis C. Travis
Page 5-23; Table 5-6
This table is interesting. I am surprised that the soil concentrations in pasture are only about 4 to 5 times greater that the soil concentrations in cropland given that inputs are mixed to 20 cm for cropland and only 2 cm for pasture. Why are not soil concentrations linear with initial concentration, which is 10 times greater for pasture than cropland?

Another surprising thing is that Buffer soil concentrations are higher than cropland. I guess this is because buffer soil concentrations are an average of input from cropland and pasture. Or is it that runoff from cropland builds up on the surface of the buffer zone? The document should be clear on this. This brings up another question. What is the mixing depth in the buffer zone?

What is the largest contributor to buffer soil concentrations, upland runoff or atmospheric deposition?

How do these soil concentrations compare to background soil concentrations? One would expect them to be higher, but how much higher? How do these soil concentrations compare with the concentrators in the sludge that was applied? In other words, how much buildup is there in soil concentrations over time as a result of biannual application of sewage sludge?

Curtis C. Travis
Page 5-23; Paragraph 2, Bullet 1
The text says, "the year during biosolids application that the farm family moves to the farm." I do not see how the year the farm family moves to the farm can affect the dioxin congener concentration in the soils. The dioxin soil concentrations are affected by other variables. It is the magnitude of exposure of the farm family is affected by when they move to the farm.

Curtis C. Travis
Page 5-23; last Paragraph
This is a good addition to the document, but it only explains why exposure depends on when the farm family moves to the farm, not why soil concentrations depend on when the farm family moves to the farm.

Curtis C. Travis
Page 5-25; Paragraph 1
The text says, "The soluble fraction are so low that they are assumed to be zero." It is not clear what this means. Does it mean the solubility of the contaminates in water is so low that the model assumes zero solute in water?

Curtis C. Travis
Page 5-27; Table 5-7
This table mentions vapor-phase deposition while equation 5-10, page 5-28, mentions air-to-plant transfer. Are they the same thing?

Robert J. Fares
Page 5-29; **Equation 5-11 Key**
For Dp, Where in the report is it calculated?

Robert J. Fares
Page 5-30; Equation 5-12 key
For Cvapor, Where in the report is it calculated?

Robert J. Fares
Page 5-30; Table 5-8
Concentrations are missing.

Curtis C. Travis
Page 5-30; Table 5-8
There are no values given in Table 5-8

Robert J. Fares
Page 5-31
Equation 5-13 key. For Csoil, Where in the report is it calculated?

Robert J. Fares
Page 5-31
Equation 5-13 key. For Kd, Where in the report is it calculated?

Curtis C. Travis
Page 5-31; Table 5-9
How do the concentrations given in Table 5-9 compare with background TCDD concentrations is fruits and vegetables?

Robert J. Fares
Page 5-32; Table 5-10
Concentrations are missing.

Curtis C. Travis
Page 5-32; Table 5-10
There are no values in this table.

Robert J. Fares
Page 5-34
Equation 5-14 key. For Pforage, Where in the report is it calculated?

Robert J. Fares
Page 5-34
Equation 5-14 key. For Pfeed, Where in the report is it calculated?

Curtis C. Travis
Page 5-34 and 5-35
Equations 5-14 and 5-15 appear to be correct.

Robert J. Fares
Page 5-35
Equation 5-15 key. For Pforage, Where in the report is it calculated?

Robert J. Fares
Page 5-35
Equation 5-15 key. For Pfeed, Where in the report is it calculated?

Robert J. Fares
Page 5-36; Table 5-12
Concentrations are missing.

Curtis C. Travis
Page 5-36; Table 5-12
There are no values in this table.

Curtis C. Travis
Page 5-36; Table 5-13
How do these values compare with background TCDD concentrations in beef?

Robert J. Fares
Page 5-37; Table 5-14
Concentrations are missing.

Curtis C. Travis
Page 5-37; Table 5-14
There are no values in this table.

Curtis C. Travis
Page 5-37; Table 5-15
How do these values compare with background TCDD concentrations in milk?

Robert J. Fares
Page 5-38; Table 5-16
Concentrations are missing.

Curtis C. Travis
Page 5-38; Table 5-16
There are no values in this table.

Robert J. Fares
Page 5-39; Equation 5-16 key
For Pforage, Where in the report is it calculated?

Curtis C. Travis
Page 5-39; Equation 5-16
This equation appears to be correct.

Curtis C. Travis
Page 5-41; Table 5-17
The ratio between the 95th percentile and the 50th percentile concentration is 4.05 for poultry thigh meat, while it is 4.5 for beef and 4.8 for milk. Why is the probability distribution for TCDD concentration in poultry thigh meat different than that for beef and milk? Is this simply due to statistical variation in the Monte Carlo method?

Robert J. Fares
Page 5-41; Table 5-18
Concentrations are missing.

Curtis C. Travis
Page 5-41; Table 5-18
There are no values in this table.

Curtis C. Travis
Page 5-42; Table 5-19
The ratio between the 95th percentile and the 50th percentile concentration for eggs is 3.8. This is even farther off than poultry thigh meat. Can the difference depend on the fact that poultry thigh meat and egg concentrations depend mainly on soil concentrations, while beef and milk concentrations depend mainly on air vapor concentrations, and that the distributions for air vapor concentrations are slightly wider that those for soil concentrations due to greater differences in temperatures across the U.S.?

Robert J. Fares
Page 5-43; Equation 5-16
Change "BASF" to "BSAF".

Robe rt J. Fares
Page 5-43; Equation 5-16 key
Change "BASF" to "BSAF".

Curtis C. Travis
Page 5-43; Equation 5-18
This equation appears to be correct.

Curtis C. Travis
Page 6-2; Section 6.1
The receptors and exposure pathways in Table 6-1 appear appropriate.

Paul S. Price
Section 6.1.1
The time weighted exposure parameters estimated using Equation 6-1 will lead to incorrect predictions of doses in children and should not be used. The correct approach for deriving the average exposure over time periods where a child changes is as follows:

Average Dose =

$$\text{DoseBreast milk} * D0 + \text{Dose1} * D1 + \text{Dose2} * D2 + \text{Dose3} * D3 + \text{Dose4} * D4$$
$$(D0 + D1 + D2 + D3 + D4)$$

Where each dose, dosei, is calculated using the age-specific inputs for the ith age period.

Curtis C. Travis
Page 6-4; Section 6.1.3
The exposure pathways listed in this section are appropriate.

Curtis C. Travis
Page 6-5; Ingestion of Breast Milk
The document does not say how long adult women farmers are exposed (how long they live on the farm) before they give milk to the infants. The document also does not say how long infants consume breast milk. I assume these details are coming later.

Curtis C. Travis
Page 6-7; Section 6.2.1.1
The document says, "Thus, soil ingestion rates used in the probabilistic analysis were not varied for any age group." The meaning of this sentence is not clear. It would be clearer to say, "Child soil ingestion rates were used for children in the age group 1 to 5. Adult soil ingestion rates were used for all other age groups." Since this section does not say, I assume a fixed value was used for the soil ingestion rate as apposed to a distribution. This point should be made clear.

Paul S. Price

Sections 6.2.1.2 - 6.2.1.4

The distributions of beef consumption rates are not correct and are likely to be significantly higher that actual intakes. The distributions are derived from the findings of the Nationwide Food Consumption Survey. This survey determined intakes for families and individuals over a 7-day period. In Table 13-36 of the EFH, EPA used the results to estimate the intake rate of beef. The approach used by the agency in developing the data for this table was only to use data from homes that had consumed beef during the week they were surveyed (Consumers Only).

There are two problems with the data. First, the method used by EPA has the potential to over estimate the intake at the upper portion of the distribution and underestimate the intake at the lower end. This potential for over estimation can be seen in the data in the following table. In this table, the reported intake is taken directly from the EFH table 13-36 and then converted to more understandable measures of intake.

Percentile	Reported Intake	Body weight (kg)	Daily intake	Daily intake	Beef meals consumed per
	Adults (20-39)				
50	1.59	70	111.3	0.30	4.3
90	4.88	70	341.6	0.94	13.1
95	6.5	70	455	1.25	17.5
99	8.26	70	578.2	1.58	22.2
100	8.26	70	578.2	1.58	22.2
	Children 6-11				
50	2.11	30	63.3	0.17	2.4
90	11.4	30	342	0.94	13.1
95	12.5	30	375	1.03	14.4
99	13.3	30	399	1.09	15.3
100	13.3	30	399	1.09	15.3

As the table indicates, the top ten percent of the population of children and adults are predicted to eat little else then beef (more then 2 meals a day every day)[2]. This assumption, while conservative, is not out of the question for any one-week period of a person's life. (It would reflect an unhealthy but not impossible diet.)

Second, the model developed by EPA assigns a single value of beef intake to each simulated individual for the entire duration of his or her exposures. This implies that a farm family must always eat beef at least once a week. It also implies that >10% of the population will have multiple beef meals each and every day for years.

The net result of these two problems is that the model over estimates beef intake at the higher percentiles. Since the beef pathway was found to be the driver for this risk assessment this is a critical flaw that must be addressed by EPA prior to using the analysis in a regulation.

The problem facing EPA is trying to estimate the distribution from chronic exposure using data on consumption patterns from short-term surveys (seven days or less). This problem is not unique to this

[2] Some of this over estimation is due to lower than average body weights. But even assuming a body weight of 50 kg in adults the top 10 percent still eat two beef meals a day.

assessment. There is very little data on chronic patterns of intake. Simulation models have been developed for estimating chronic exposures may be helpful (http://www.hrilifeline.org/).

Data on distribution has also been developed by the State of California (http://www.oehha.ca.gov/air/hot_spots/pdf/execsumm.pdf). USDA has also collected data on annual beef consumption rates (on a farm basis) as part of it collection of annual agricultural statistics. This data on annual consumption rates of home-raised beef is updated annually.

Finally, similar problems also happen with milk, poultry, and other food intake distributions.

Paul S. Price
Section 6.2.1.7
Average inhalation rates can be modeled as a function of age, body weight (Layton, 1993-see exposure factor handbook for the reference.) This method is preferable to the independent selection of inhalation rates. However, since inhalation does not appear to be an important pathway the change may not be worthwhile.

Paul S. Price
Section 6.2.2.1
The adoption of value of an exposure input for a child in one age group will be correlated with the values the child will have when her or she enters older age groups. For example an above average weight child at age 5 is likely to be above average weight when they are 15. The model should consider this correlation when modeling a child over time. If the model randomly picks body weight for the different age periods, it may result in a child's body weight actually going down with age.

One way to deal with this issue is to link the relative percentiles taken for each age group. Thus, if a child is in the fifth percentile of body weight in one age group they will be in the fifth percentile of each of the subsequent age groups.

Paul S. Price
Section 6.2.1.5
The risk assessment for fish ingestion assumes that the fish will be taken from a small but fishable stream. The fish consumption rate used in the analysis is taken from Maine survey data as presented in the EFH. The distribution in EFH is based on the raw data from (Ebert et al, 1994). Ebert et al. includes multiple distributions for fish consumption. One distribution is specific to fish caught in streams and rivers. This distribution should be used rather than the general distribution given in the EFH, which includes fish taken from ponds, lakes, and reservoirs.

Robert J. Fares
Page 6-8; Table 6-4
Footnote "Pop-Estd Mean" and "Pop-Estd SDev" values for Gamma distribution indicating that they represent "Pop-Estd Shape" and "Pop-Estd Scale" values.

Curtis C. Travis
Page 6-8; Table 6-4
It is not clear if these distributions are appropriate. How was the fraction of exposed fruit intake that is home-grown used in obtaining this table? Does one first obtain the distribution for each age group using Table 13-61 of the EFH (U.S. EPA, 1997b) and then multiply by 0.328 for households that farm and 0.116 for households that garden? How do you know that P90 and P95 exposures do not exceed what is reasonable

given the average (or maximum) fruit intake of a normal person and the fact that only a fraction of fruit intake comes from the farm?

I find it hard to believe that the average farm household produces 32.8 percent of their fruit intake. The most common fruits eaten by people are bananas, apples, oranges, and peaches. These are not grown on the average farm. Thus, they will not be home grown on most farms. Farm households do produce watermelon, cantaloupes, and berries, but I doubt that these makeup 32.8 % of farm family intake of fruit. Another question is, what percentage of farm families do not produce any fruit on their farm? Many farms that people live on only produce cattle or dairy cows. If they do have a garden, they do not grow apples, oranges, bananas, peaches, etc. Small gardens are usually for vegetables, but not fruit. And at least some fraction of farms would grow no fruit in their gardens. This kind of information should be available for the Department of Agriculture. A quick search found that Virginia has 49,000 farms, but only 751 that produce fruits, nuts and berries. Thus, only 1.5% of Virginia farms grow fruit, but the current assessment assumes that 32.8 percent of fruit intake is homegrown for households that farm.

On page 6-3 the document says, the reason for considering children separately is that they consume more per unit body weight. However, Table 6-4 shows the mean intake of a 1 to 5 year old child to be about the same as an adult. If anything, these numbers show lower intake for children (the 12 to 19 age group).

Curtis C. Travis
Table 6-4
In Table 6-4, is the mean the best way to characterize the "average" distribution value? Since these are lognormal distributions, why not use the geometric mean?

What does the Max mean in table 6-4? Are the distributions truncated at the value given by Max?

Curtis C. Travis
Page 6-9; Figure 6-2
What does the black triangle mean in these figures? It does not correspond to the Max value given in Table 6-4, thus it's meaning is not clear.

Curtis C. Travis
Page 6-9; Table 6-5
What is the basis for the central tendency number in this table? The adult central tendency is 1.36 as compared to a mean of 2.36 in Table 6-4. What is the statistical definition of the high-end exposure? It does not appear to be either a 90th or 95th percentile (as defined in Table 6-4).

Robert J. Fares
Page 6-10; Table 6-6
Footnote "Pop-Estd Mean" and "Pop-Estd SDev" values for Gamma distributions indicating that they represent "Pop-Estd Shape" and "Pop-Estd Scale" values.

Curtis C. Travis
Page 6-10
I have the same questions about Table 6-6 and Figure 6-3 and Table 6-7 that I had on the tables and figures in the previous section. At least for vegetable consumption, children 1 to 5 are consuming more on a per weight basis than adults. The high end exposure for the child and adult in Table 6-7 appears to be less than the 90th percentile in Table 6-6. Why is this?

Robert J. Fares
Page 6-11; Table 6-8
Footnote "Pop-Estd Mean" and "Pop-Estd SDev" values for Weibull distributions indicating that they represent "Pop-Estd Shape" and "Pop-Estd Scale" values.

Curtis C. Travis
Page 6-11
I have the same questions about Table 6-8, Figure 6-4, and Table 6-9 as before. The high-end exposure for adults in Table 6-9 is the 90th percentile. Why in this case but not the others?

Robert J. Fares
Page 6-13; Table 6-10
Footnote "Pop-Estd Mean" and "Pop-Estd SDev" values for Gamma distribution indicating that they represent "Pop-Estd Shape" and "Pop-Estd Scale" values.

Curtis C. Travis
Page 6-15; Table 6-12
The text says that CSFII data were used to generate the dairy consumption distributions. If this is so why are the distribution characteristics filled in in Table 6-12 for the HP and EFH(HP) data, but no the CSFII data?

Curtis C. Travis
It is not clear what Population Estimated Scale means in Table 6-12.

Curtis C. Travis
Page 6-16; Last Sentence
The text says that 25.4% of farm households consume home-produced dairy product. I do not believe that 25.4% of farm households in the U.S. raise dairy cattle and obtain their daily products from them. For one thing, many parts of the country, like the southwest, are not particularly conducive to growing dairy cattle. There are about 2 million farms in the United States and only about 100,000 are licensed to produce milk. This means that less than 5% of farms in the United States are licensed to produce milk. A quick search found that Virginia has 49,000 farms, but only 1,296 that produce dairy products. Thus, only 2.6% of Virginia farms produce dairy products, but the current assessment assumes that 25.4 percent of dairy product intake is homegrown for households that farm.

Curtis C. Travis
Page 6-17; Table 6-13
The central tendency numbers in this table seem too high. They are greater than the 95th percentile in Table 6-12. For instance, the central tendency for adults is given as 12.6, while table 6-12 lists the 95th percentile as 9.88. How can the central tendency be larger than the 95th percentile? Also the high-end numbers also appear high. For example, 90.2 for the child is off the scale of anything that appears in Table 6-12. Same for the adult.

Curtis C. Travis
Page 6-19; Paragraph 1
The fraction of poultry that is home produced is 0.156. This number seems more reasonable than the 0.254 for dairy products. If anything, the poultry number of 0.156 calls into question the dairy number of 0.254 because chickens are much easier to grow on a farm than dairy cows.

Curtis C. Travis
Page 6-19; Table 6-15
The central tendency and high-end numbers in table 67-15 do not match with the numbers given in table 6-14.

Curtis C. Travis
Page 6-22; Paragraph 1
It is hard to believe that adult fishers catch 32.5% of the fish they eat close to their own farm. It is harder to believe that they catch 64% of the T4 fish they consume close to their own farm.

Curtis C. Travis
Page 6-23; Paragraph 1
The use of a triangular distribution is reasonable.

Curtis C. Travis
Page 6-23; Table 6-21
Why is the central tendency in this table given as 687, while in Figure 6-10 and in Table 6-20 it is given as 688? How can the high-end consumption be the same as the central tendency, while figure 6-10 shows a high-end consumption of 1,376?

Robert J. Fares
Page 6-27; Table 6-24
Footnote "Pop-Estd Mean" and "Pop-Estd SDev" values for Gamma distribution indicating that they represent "Pop-Estd Shape" and "Pop-Estd Scale" values.

Curtis C. Travis
Page 6-30; Paragraph 1
The approach to averaging time seems reasonable.

Robert J. Fares
Page 7-2; Table 7-1
Concentrations and TEQ values are missing.

Curtis C. Travis
Page 7-2; Table 7-1
Table 7-1 has no data in it.

Curtis C. Travis
Page 7-3; Soil Ingestion
It is not clear if the soil for the soil ingestion risk assessment was taken from the buffer zone (where the farmer is assumed to live) or from the crop production area. The buffer zone would be more appropriate. It is not clear if the elevated soil concentrations resulting from many years of application were used or if the soil concentration resulting from one application was used.

Curtis C. Travis
Page 7-4; Section 7.1.3.2
These calculations appear to be appropriate and correct.

Curtis C. Travis
Page 7-7; Paragraph 1
Why are the 90th percentile risk levels given for beef, but the 95th percentile risk levels are given for poultry and eggs? This inconsistence makes it appear as though the document is trying to understate the risk from beef consumption. The same is true for milk in section 7.1.3.6.

Curtis C. Travis
Page 7-10; Table 7-11
These risks seem low. I thought breast milk ingestion was a high-risk pathway for exposure. In the Dioxin reassessment, EPA found high risk from this pathway from background exposures. Why does it turn out to be low in the case of sewage sledge application?

Curtis C. Travis
Page 7-10; Section 7.2
You should restate the target risk level. I assume it is 1.0 E-5.

Curtis C. Travis
Page 7-10; Section 7.2.1
The text says, "This scaling approach is allowable since all of the modeling results in the analysis were linear with respect to the initial biosolids concentration." I don't believe that this statement is true. The document seems to indicate that air and soil concentrations are nonlinear with farm size, as indicated on page 5-17, last section and page 5-24, paragraph 1. This point needs to be made clear in the document.

Curtis C. Travis
Page 7-10; Equation 7-2
The use of equations 7-2 and 7-3 is correct and appropriate.

Robert J. Fares
Page 7-11; Table 7-12
Risks and Risk-Limiting Concentrations are missing.

Curtis C. Travis
Page 7-11; table 7-12
There are no numbers in this table.

Curtis C. Travis
Page 7-12; Section 7.3
The description of the probabilistic approach taken in this section is not adequate. More detail needs to be given as was done in section 4.0 of this document. It is not clear how a distribution of concentrations for dioxin in sewage sledge was obtained. Nor is it clear how the distribution was applied to arrive at risk. Were distributions of sewage sledge concentrations used along with distributions of exposure factors to arrive at a totally probabilistic approach to calculating the actual risk associated with current concentrations of dioxin in sewage sludge?

Robert J. Fares

Page 7-13; Paragraph 4; Line 1
If the data in Table 7-16 is correct, change "shows risk" to "shows no risk".

Curtis C. Travis
Pages 7-13 through 7-16
Why are the risks using this method of calculation (I guess this method is using the actual distribution of concentrations of dioxin in sewage sledge rather than a single concentration, but it is not clear that this is the case) lower than the risks obtained using a single sample (section 7.1)? Was the sample selected in section 7.1 at the upper end of the distribution of measured concentrations in sewage sledge?

Robert J. Fares
Page 7-14; Paragraph 2; Line 1
If the data in Table 7-17 is correct, change "shows risk" to "shows no risk".

Robert J. Fares
Page 7-14; Paragraph 4; Line 1
If the data in Table 7-18 is correct, change "shows risk" to "shows no risk".

Paul S. Price
Table 7-18
Typo for the Child - 90th percentile.

Curtis C. Travis
Page 8-1
This page is clear.

Curtis C. Travis
Page 8-2; Paragraph 5
The document says, "However, uncertainty about farm size within a climatic region remained." If you want to be consistent with your own usage of terms, it is not uncertainty that remains, but variability. Thus the sentence could say, "However, variability of farm size within a climatic region was not characterized."

The paragraph also says, "Distributions were used to capture nationwide variability in agricultural practices." What is this sentence referring to? What farm practices, sewage sledge application rates? What else is there that you used distributions for?

I assume that one of the 41 climate regions was picked at random and them the rest of the modeling was done on the characteristics of this region and that this process was repeated 3,000 times. This approach gives equal weight to all climate regions in the U.S. However, choice of climate region for each iteration should have been by the number of farms in that region.

Curtis C. Travis
Page 8-3; Section 8.1.2.1
I agree that use of the 41 climate regions provides a reasonable representation of the variability in meteorological conditions in the Untied States.

Curtis C. Travis
Page 8-4; Section 8.1.2.5
I agree that probabilistic approach used in this assessment provides a reasonable approach to assessing the risk for dioxins, furans, and PCBs in biosolids. I believe that the EPA has made an excellent effort to capture most of the variability present in exposure to biosolids. Also when uncertainties existed in the variability, EPA tended to overestimate upper end exposures.

Curtis C. Travis
Page 8-4; Section 8.1.2.6; Paragraph 1
This paragraph is not very clear. There must be a clearer way the describe what a response surface is. The paragraph says, "This methodology is referred to as a response surface regression approach because it uses models characteristic of those used in a response surface experiments." This sentence is not clear. What does it mean to "use models characteristic of those used…" What models?

The text also says, " The terminology "response surface" derives from the fact that a regression model involving a number of continuous independent variables can be viewed as …" How does a regression model fit into a sensitivity analysis? There is not enough detail in your description for the uninitiated to follow what you are saying.

The text also says, "The complexity of the model (e.g., whether it contains only first-and second-order terms…" What model are you talking about, the "model estimation methodology", "the regression model", or "the environmental transport and exposure models" used in this document?

Curtis C. Travis
Page 8-4; Section 8.1.2.6; Paragraph 2
The text says, "This methodology is one of the recommended methods for conducting a sensitivity analysis based on the results of a Monte Carlo analysis." Why does the sensitivity analysis have to be based on the results of a Monte Carlo analysis? I thought that the sensitivity analysis could be done independent of the Monte Carlo analysis.

Curtis C. Travis
Page 8-4; Section 8.1.2.6; Paragraph 3
The text says, When the risk depends on the aggregate impact…may not necessarily identity the most important one." What does the "one" refer to?

Curtis C. Travis
Page 8-5; Entire Page after the Bullets
This entire section is written poorly and is very unclear.

Curtis C. Travis
Page 8-6; Paragraph 3
The text says, " FMSS = model sum of squares for the final model" What does the sum of squares for the final model mean? How is it defined? What model are you talking about, the regression model or the original model?

Similarly, the text says, "ERSS = model error sum of squares" How is the model error calculated?

The text says, "The two parameters responsible for the largest percentage of the risk are the two parameters

set to high-end values in the deterministic analysis." For all of the exposure parameters, the high-end values were defined in tables given in Chapter 6. What is the above sentence referring to, the environmental transport part of the analysis?

Curtis C. Travis
Page 8-7; Third Bullet
The text says, "Develop a model for Log (environmental concentration) based on the results of the regression analysis." What kind of model, regression model as defined by equation 8-1?

Curtis C. Travis
Page 8-8; Paragraph 1; Equation 8-4
This equation makes clear that when the document talks about a model in many places above, it is talking about the model to produce the environmental concentration. This point should be made clear earlier. It would make things easier to understand.

Curtis C. Travis
Page 8-8; Bullet
The text says, "Because the final model will most likely contain first- and second- order terms involving…" What is the term "final model" referring to? To often in this section on sensitivity testing the document refers to a model without stating what model is being referred to. This is confusing for the reader. This entire section needs to be written more clearly.

The text says, "FMSS = model sum of squares for full model containing all significant terms" What is the full model? Are you referring to Equation 8-4 with the log (environmental concentration) term replaced by the regression model? These things need to be made clear. For example, you could say at the end of paragraph 1, "Hence forth, Equation 8-4 with the log (environmental concentration) term replaced by the regression model of input variables will be called the full model." I would not use the term "final model" here (see comment above).

The text says, "RMSS and RMDF = model sum of squares and degrees of freedom for reduced model." What does model sum of squares mean? What does model degrees of freedom mean? What is reduced model?

The text says, "FMDF = model degrees of freedom for full model." What does model degrees of freedom mean? What is the full model?

The text says, "The full model refers to the model containing all significant terms in the final log (risk) model." This sentence would be clearer if the document used the definition of full model given above. As it is, it uses the word "model" in three places with different meanings.

Curtis C. Travis
Page 8-9; Paragraph 4
The text says, "These are reasonable assumptions; however, much uncertainty is associated with the scenario." Give some examples of uncertainties associated with this scenario. You might say, for example, "Some farms may only have cropland, some farms may only have pasture, some farms may not have a stream, and in some farm situations the family may live up gradient from the cropland and pasture. However, the scenario chosen is believed to represent a reasonable bounding scenario for evaluation of the farm application of sewage sledge."

Curtis C. Travis
Page 8-10; Table 8-1
This table is interesting and a positive addition to the document. However, since exposure duration, consumption rate, and application rate show up in nearly every pathway, the table does not provide much information about the physical parameters that are important in the modeling effort. It would be beneficial to add two more parameters to each pathway (this may necessitate expanding the table to two pages) so that other important parameters could be identified.

Curtis C. Travis
Page 8-11; Section 8.2.1.5
While background dioxin exposures may vary over the United States, the dioxin reassessment document gave a good characterization of background risk from dioxin.

Curtis C. Travis
Page 8-12; Paragraph 3
This paragraph and Figure 8-1 are good additions to the document.

Robert J. Fares
Appendix B; Page 2; Paragraph 6; Lines 1-2
Change "P[Bh/Ah]" to "P[Bh|Ah]".

Curtis C. Travis
Appendix C
The parameters in this appendix appear to be reasonable and well documented. They appear to be appropriate for the scenarios being modeled and for a national level assessment. The parameter effdust used a normal distribution to describe its variability. A triangular distribution would have done just as well. It is not clear what the parameters zava (Upper depth average soil concentration) and zavb (Lower depth average soil concentration) refer to. The format of this table is excellent. It provides a concise overview of the parameter values, their variability, and documentation.

Robert J. Fares
Appendix C; Page 3; Paragraph 6
Change "enchrichment" to "enrichment".

Robert J. Fares
Appendix C; Page 6; Paragraph 4
If the assumption for "veg" is based on professional judgment how can the authors justify a Normal distribution? That implies that enough is known about the data that professional judgement would not be necessary. Please explain.

Curtis C. Travis
Appendix D
Parameters in Table D-1 appear standard and appropriate for this assessment.

Robert J. Fares
Appendix D; Page 4; Paragraph 2; Lines 5-7
The authors used an equation that relies only on the molecular weight of a chemical to calculate diffusivity in water. Why didn't they consider the procedure described by Lyman et al. (1990)?

Curtis C. Travis
Appendix D; Page D-5
The assumption of zero degradation and hydrolysis is appropriate, but means that very little dioxin is lost from soil after application.

Curtis C. Travis
Appendix D; Page D-5
The assumption of a 0.6 fraction of wet deposition adhering to plant surface and a plant surface loss coefficient for particulates of 18.07 1/yr means that about 60% of dioxin in air is transferred to plants during rain events. This seems somewhat high, but I have no data to indicate otherwise. It would be nice if the document would tell what percentage of dioxin taken up by exposed plants is from deposition and what percentage is from vapor air-to-plant transfer. It is generally believed that vapor air-to-plant transfer is the dominant pathway, although little actual data are available.

The chemical-specific parameters given in Tables D-2 through D-30 appear appropriate.

Curtis C. Travis
Appendix D; Table D-3
The bioconcentration factor for cattle and poultry, and the biota-to-sediment accumulation factor seem low. The organic carbon partition coefficient for this chemical is higher than for the chemical in Table D-2, but the above parameters are lower.

Curtis C. Travis
Appendix D; Table D-5
The bioconcentration factor for poultry seems low. It is lower than the bioconcentration factor for beef. For all other chemicals in this section, the bioconcentration factor for poultry in higher than the bioconcentration factor for beef.

Curtis C. Travis
Appendix D; Table D-10.
It does not seem appropriate to use two significant figures (2.69) in the value for the bioconcentration factor for cattle. This number should be given as 2.7. This same use of too many significant figures occurs in several of the tables.

Curtis C. Travis
Appendix D; Table D-14 and D-15
It is not clear why these two chemicals have the same organic carbon partition coefficients, the same soil water partition coefficients, the same air-to-plant biotransfer factors, and the same bioconcentration factors for cattle, but different bioconcentration factors for poultry and eggs. I realize that the reference given is the 2000 dioxin reassessment, which is suppose to be the most up to date document on dioxin and its properties, but this discrepancy does not make sense.

Curtis C. Travis
Appendix E
The parameters in this appendix appear to be reasonable and appropriate. However, without checking the original references, it is impossible to tell if they are correct. The farm sizes appear large. That is because they represent average size farms and farm sizes have increased over the years as farms become more commercial rather than family owned. It is probable that these farms sizes over estimate the size of farms that

actually have farm families living on them. However, using these farm sizes should provide a conservative estimate of the risk of using sewage sledge on farmland.

Curtis C. Travis
Appendix F; Page F-1
The document says, " A source term module was developed for land application units (LAUs) to provide estimates of annual average surface soil constituent concentrations and constituent mass emission rates to air and ground water." The end of this sentence should say "…constituent mass emission rates to air, downslope land, surface streams, and ground water."

Curtis C. Travis
Appendix F; Page F-3
This approach to estimating contaminant partitioning into the solid, liquid, and gaseous phases of soil is reasonable and appropriate for the scale of assessment being performed. This is a standard approach to modeling soil concentrations and is widely used in the assessment area. This approach also accounts for leaching of contaminate downward towards ground water due of rain water infiltration.

Robert J. Fares
Appendix F; Page iv
Appendix F has four appendices (A, B, C, D). Please consider renaming them (F-A, F-B, F-C, F-D) to avoid confusion with the other Appendices in this document.

Curtis C. Travis
Appendix F; Page F-6
It is not clear why the effective solute convection velocity (Ve) is equal to Ve = 1/KTL. Why does not the infiltration rate (I) inter into this calculation? (I now see that it is an I in equation 2-10 and not a 1. This should be made clear to avoid confusion.)

Curtis C. Travis
Appendix F; Page F-7; Paragraph 2
The quasi-analytical approach introduced a tradeoff between the ability to evaluate short-term and long-term concentrations. The approach allows evaluations of long-term concentrations, but not short-term concentrations. This is appropriate for the assessment at hand since dioxin is relatively immobile in soils and builds up over time. Thus, the long-term focus is appropriate.

Curtis C. Travis
Appendix F; Page F-7; Section 2.4.2
This section is a good addition to the document, but I'm not sure how much new insight it adds to reader understanding. It is probably too mathematical for the average reader. The most interesting sentence is on the bottom of page F-10 and says, "While the contaminant mass in the gas phase volatilizes out the surface of the soil column, the contaminant mass in the aqueous phase is left behind..." I'm not sure this is what actually happens. One would think that volatile contaminate would evaporate along with soil water.

The introduction to this section does not provide a good understanding of how the sequential solution to the three-component differential equations works. Is each of equations 2-13,2-14, 2-15 solved in sequence and then added together? How can convection be done before first-order decay? Without the decay term calculated, the concentration of contaminate in a layer would be too high and the convection equation (equation 2-14) would convect too much contaminate out of the layer. Or does this not mater because the errors are small? The document needs a few sentences to explain this. (I now see that you have an

explanation on page F-13, but some introduction is need here since many readers will not look at the detail of section 2.4.2.2).

Curtis C. Travis
Appendix F; Page F-11; Paragraph 5
The text says, "This component of numerical diffusion can be avoided completely if the contents of each layer are transferred completely to the next layer at the end of each time step…" The meaning of this sentence is not clear. Is the total content of each layer transferred or just the amount that is supposed to be convected? It does not make sense that everything in a layer would be convected out of that layer with each time step. It is also not clear making the time step equal to the layer thickness divided by the effective velocity solves the problem. You need a little more explanation.

Curtis C. Travis
Appendix F; Page F-14; Section 2.5
This is a good addition to the document.

Curtis C. Travis
Appendix F; Page F-14; Section 2.5; First Bullet
The text says, "This complexity is not modeled by the GSCM for metals partitioning; rather Kd is externally provided as a randomly sampled value…" This makes it sound like this is a procedure followed just for metals to over come the problem with Kds for metals. Isn't this same procedure done for organic chemicals also?

Curtis C. Travis
Appendix F; Page F-14; Section 2.5; Second Bullet
I agree that under normal conditions of land application, you should not have pure contaminate (precipitate) present. However, it is good that the model checks for this.

Curtis C. Travis
Appendix F; Page F-16; Paragraph 2
I agree that the assumption of sheet-flow only is reasonable.

Curtis C. Travis
Appendix F; Page F-16; Paragraph 3
This is the first time in the document that there is mention of multiple subareas downslope from the LAU. How are they used in the analysis? It is assumed that the farmer lives in the buffer zone. Which subarea of the buffer zones does he live in? What is the purpose for having multiple subareas? Why no just have one long buffer zone? There must be a reason for going to these extra trouble, but the document does not explain it.

Curtis C. Travis
Appendix F; Page F-19; Paragraph 1
CN is not defined. I can guess that CN means curve number.
What is a curve number? What does, "and initial abstraction as a function of storage", mean in the first sentence?

Curtis C. Travis
Appendix F; Page F-20; Last Paragraph; Psuedo-code
The text says, "Cneff = area-weighted composite Cni for all subareas" From Table 3-1, CN only appears to depend on soil moisture (although, one would think it would also depend on soil type, but if so, the text does not explain this). Assuming CN only depends on soil moisture, why would the soil moisture conditions for the different subareas be different, they are all right next to each other and thus would receive the same antecedent moisture conditions?

Curtis C. Travis
Appendix F; Page F-24; Equation 3-19
The document does not explain how the slope angles are chosen. Do they change for each subarea? Are they the same for all subareas? Are they chosen at random from a distribution or are they constant throughout the application?

Curtis C. Travis
Appendix F; Page F-26; Section 3.3.3
The document does not explain where the K,C,P values come from. Each farm is located within one of the 41 climate regions. Are the K,C,P values averages for the climate region? If so, how do you get different values of K,C,P to obtain an area-weighted value for all subareas? What about spatial variability of LS? How is that accomplished? How is LS (or the slope angle) made to be representative of the climate region?

Curtis C. Travis
Appendix F; Page F-46; Section 3.7.2
I agree with the assumptions made in this section.

Curtis C. Travis
Appendix F; Page F-60; Section B.2
The text says, "The reference air diffusivity…" The symbols in "(Dar)" are hard to read in this sentence.

Curtis C. Travis
Appendix F; Page F-66; Table C-1
The terms LF cell and WP are not defined. In footnote C, the text says, "For a description of how results for whole LF are obtained from LF cell results, see Section 4.5" There is no section 4.5 in this report.

Robert J. Fares
Appendix F-78; Paragraph 4; Line 2
Change "previously used the LAU" to "previously used in the LAU".

Curtis C. Travis
Appendix F; Page F-79; Section D.2.4
I agree that assuming mixing of the soil column in pasture is a shortcoming of the current approach, but it should not produce a very large error. Moreover, the groundwater pathway is not a major pathways of exposure dioxin and thus, this error is not serious. If groundwater was a more important pathway, another approach could be taken to the modeling pasture soil, but it is not necessary in this case.

Curtis C. Travis
Appendix G; Page G-4; Paragraph 2
The use of averages over a 3-km radius appears appropriate. The current assessment is only interested in impacts in the vicinity of the land application site, e.g., the farm family and deposition in the buffer zone.

Curtis C. Travis
Appendix G; Page G-4; last Paragraph
Assuming zero for the anthropogenic heat flux at the farm locations appears appropriate. It is unlikely that such farms are in highly urbanized locations.
Curtis C. Travis
Appendix G; Page G-5 through G-8
The parameters in the various tables appear reasonable.
Curtis C. Travis
Appendix H
The Tables in this Appendix all refer to Appendix K as a source of parameters. This is incorrect. Appendix K is on the sensitivity analysis.

Curtis C. Travis
Appendix H; Page H-4
This calculation appears correct.

Curtis C. Travis
Appendix H; Page H-5
I found all of these parameters in Table J-2. The formula is more complicated than it needs to be since the assessment assumes the concentration of contaminant in the aqueous phase of maternal milk is zero. Why not just state this assumption and get rid of the corresponding terms in the equation?

Curtis C. Travis
Appendix H; Page H-6
The Table states that the value for the fraction of air concentration in vapor phase is given in Appendix D. I cannot find it there. For example, see Table D-2 where there is no mention of this parameter.

Curtis C. Travis
Appendix H; Page H-12
The parameter Fv cannot be found in Appendix D.

Curtis C. Travis
Appendix H; Page H-13
The parameters Fv and Vdv cannot be found in Appendix D. None of the parameters cited as being in Appendix G can be found in that Appendix. Why not just say calculated by Air Model.

Curtis C. Travis
Appendix H; Page H-14
None of these parameters are found in locations cited.

Curtis C. Travis
Appendix H; Page H-15
None of these parameters are found in locations cited.

Curtis C. Travis
Appendix H; Page H-16
The values for the area of the local and regional watershed are not given in Appendix E, Table E-1, page E-3. There is one watershed area given in Table E-1, but it is not clear if it is for the local watershed, the regional watershed, or both.

Paul S. Price
Appendix H Table H 2-5
EPA and RTI should be congratulated on the model of start age for the Monte carol analysis of the population. By randomly selecting a "start year" for an individual year 1-40, then selecting the duration for the individual and then calculating the average concentration for the duration they are modeling the exposed population correctly.

Paul S. Price
Appendix H Tables H-2.3 and 2.4
The average soil concentration should be determined by averaging the soil concentration for each year between first and the last year of exposure.

Curtis C. Travis
Appendix H; Page H-21
I'm not sure that ER, the soil enrichment ratio, is in Appendix J. I could not find it. This needs to be checked. Here reference is made to Appendix E for the total watershed area. How is this parameter related to the local and regional watershed areas mentioned in Table H-2.11 on page H-16?

Curtis C. Travis
Appendix H; Page H-25
The soil bulk density is not given in Appendix E.

Robert J. Fares
Appendix H; Page 26
Table H-2.21 key. Merge the last two descriptions to read as "Empirical slope coefficient related to the power of the drainage area. B = 0.125 (unitless)"

Robert J. Fares
Appendix H-Page 28; Table H-2.23 key
Where in the report are the values for parameters "a" and "b" located?

Robert J. Fares
Appendix H-Page 30; Table H-3.1 key
For Pfeed, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 30; Table H-3.1 key
For Pforage, Where in the report is it calculated?

Curtis C. Travis
Page H-30

Bs gives bioavailability of contaminant in soil relative to vegetation, and the parameter is in Appendix I as stated. However, what is the bioavailability of contaminant in vegetative vehicle? I assume from the equation that it is 100%. Why is the parameter Bs defined as the bioavailability of contaminant in soil relative to vegetation rather than just the bioavailability of contaminant in soil? You might want to explain this back in the text.

Robert J. Fares
Appendix H; Page 31; Table H-3.2 key
For Pfeed, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 31; Table H-3.2 key
For Pforage, Where in the report is it calculated?

Curtis C. Travis
Appendix H; Page H-31
These equations appear correct.

Robert J. Fares
Appendix H; Page 32; Table H-3.3 key
For Pfeed, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 32; Table H-3.3 key
For Pforage, Where in the report is it calculated?

Curtis C. Travis
Appendix H; Pages H-32, 33, and 34
These equations appear correct.

Robert J. Fares
Appendix H; Page 33; Table H-3.4 key
For Pfeed, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 33; Table H-3.4 key
For Pforage, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 34; Table H-3.5
Change "BASF" to "BSAF".

Robert J. Fares
Appendix H; Page 36; Table H-3.7 key
For P_exfruit, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 36; Table H-3.7 key
For P_exveg, Where in the report is it calculated?

Curtis C. Travis
Appendix H; Page H-36, 37, 38, 39, 40
All of these tables mention Appendix K as the source of data. Appendix K is the sensitivity analysis.

Robert J. Fares
Appendix H; Page 39; Table H-3.10 key
For C_fishT3F, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 39; Table H-3.10 key
For C_fishT4F, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 39; Table H-3.10 key
Change "CRf" to "Crfish".

Robert J. Fares
Appendix H, Page 42; Table H-3.14 key
For Csoil, Where in the report is it calculated?

Robert J. Fares
Appendix H; Page 45; Note; Line 1; Table H-3.16 Key
Change "vegetataion" to "vegetation".

Robert J. Fares
Appendix H; Page 45; Note; Line 2; Table H-3.16 Key
Change "vegetataion" to "vegetation".

Curtis C. Travis
Appendix H; Pages H 46, 47
These tables have the same problem with Appendix K.

Curtis C. Travis
Appendix I
The values in this appendix appear correct and reasonable. The fraction of diet from feed for beef and dairy used in the analysis make for maximum conditions. The value of zero for the fraction of diet for poultry from feed is reasonable given that it is unlikely the a farm will grow feed for poultry.

Curtis C. Travis
Appendix I; Table I-2
In Table I-2, Bs is defined as bioavailability for soil, but earlier (in appendix H) it is defined as bioavailability for soil relative to vegetation.

Curtis C. Travis
Appendix J; Page J-4; last Paragraph
I agree with using the two-parameter models instead of the three-parameter generalized gamma model.

Curtis C. Travis
Appendix J; Table J-1
The parameters in Table J-1 appear correct and appropriate.

It is highly unlikely that anyone would consume an average of 6.48 g/d of fish, 100% of which is home caught, but this should certainly give a high-end estimate of exposure from this pathway.

Curtis C. Travis
Appendix J; Page J-11; Table J-2
The parameters given in Table J-2 appear correct and appropriate.

Curtis C. Travis
Appendix J; Page J-12
The text says, "Exposure frequency was set to 350 days per year in accordance with EPA policy, assuming that residents take an average of 2 weeks' vacation time away form their homes each year." U.S. census data indicate that only about 50% of U.S. farmers work fulltime on their farms. The rest have other jobs off of their farms. However, it is true that somewhere there is the high-end farmer that works 350 days per year on his farm.

The soil ingestion rates used appear reasonable.

Curtis C. Travis
Appendix J; Page J-12; Section J.1.4
The distributions used in the assessment appear reasonable. The explanation of the distribution for fish consumption (page J-23) seems reasonable.

Curtis C. Travis
Appendix J; Page J-27
The exposure duration data appear reasonable.

Robert J. Fares
Appendix J; Page 28; Paragraph 1; Lines 10-11
The authors stated that a subsistence fisher ingestion rate was used as the maximum for the adult recreational fisher assessment. Did the authors consider using a high percentile value for recreational fishers?

Curtis C. Travis
Appendix J; Page J-28; Table J-15
These Minimum and Maximum values seem reasonable. The Maximum values appear somewhat large but ok for a high-end analysis.

Robert J. Fares
Appendix J; Page 30; Table J-15
Why did the authors assume 100 years as a maximum value for exposure duration for adult residents, children, and adult farmers? This doesn't seem realistic.

Curtis C. Travis
Appendix J; Page J-31; Table J-16
The parameters in this table appear reasonable.

Curtis C. Travis
Appendix J; Page J-31; Table J-17
The values in this table appear reasonable.

Robert J. Fares
Appendix K; Page 3; Paragraph 2; Line 1
Change "TEQ concentration" to "TEQ concentrations".

Curtis C. Travis
Appendix K; Page K-3; Section K.2
The first paragraph is not clear.

Curtis C. Travis
Appendix K; Page K-3 Paragraph 2
The text says, "In this analysis, a regression analysis is applied to a linear equation to estimate…" This is not clear. What linear equation is the regression analysis applied to?

This is the first place that the document says that the sensitivity analysis is applied to the probabilistic simulation rather than the deterministic version of the model. Is there a difference between a sensitivity analysis on a probabilistic model and one on the deterministic version of the same model? I would not think so.

Curtis C. Travis
Appendix K; Page K-3 Paragraph 3; First sentence
This sentence raises a question. Is there a difference between a sensitivity analysis that identifies the most sensitive model parameter relative to small changes in input parameters vs. sensitivity to large changes in input parameters. The sentence implies that historically sensitivity analysis is focused on the latter. I thought it was focused on the former. Which is the case? This point highlights the fact that the introduction to this section does not give a good definition of sensitivity analysis.

Curtis C. Travis
Appendix K; Page K-4; Equation K-1
The text on this page is not clear as to how this regression model is constructed. How many different points of the form (log y, x1,x2,…,xp) are used to determine the regression parameters in equation K-1? Do the values of the parameters in equation K-1 depend on the number of the points chosen? How do you know that they do not? How do you know that the points given a good representation of the model, that is, cover the range of possible outputs? None of this is discussed in your explanation.

Curtis C. Travis
Appendix K; Page K-5; Paragraph 1
If you remove some of the variables from equation K-1 and try to fit the reduced equation to the same number of points of the form (logy, x1, x2,…,xp), will this cause a problem?

Curtis C. Travis
Appendix K; Page K-5; last Paragraph; Bullet 1
The text says, "The data set must contain only one record for each Monte Carlo iteration." Since 3,000 iterations were run in the Monte Carlo analysis, does this mean that 3,000 points were used to determine the parameters in Equation K-1? If this is so, it would make the explanation on page k-4 clearer if you said so.

Curtis C. Travis
Appendix K; Bullet 2
The method uses points of the form (logy, x1,x2,…,xp) to determine a response surface of the form given by equation k-1. Why does it matter that some of the input parameters are constant? Maybe one of the constant parameters is the most sensitive parameter in the risk model. Why isn't this information important?

Curtis C. Travis
Appendix K; Page K-6; Bullet 2
Why does this matter? You want to find the risk model parameters that have the greatest impact of the risk estimate. Or are you trying to find the risk model parameters that for the same percentage change over their range have the greatest impact on the risk model output? Again, exactly what you mean by a sensitivity analysis has not been well defined in the introduction.

VI. MISCELLANEOUS COMMENTS

Paul S. Price

EPA is to be congratulated for assessing the risk by modeling each compound separately and then summing the compound specific risks to give the total risk. The focus on maintaining the mass balance for each compound in the applied sludge is also commendable.

Finally, the incorporation of all of the fate and transport modeling into the Monte Carlo analysis is an impressive achievement.

VII. ADDITIONAL REFERENCES

Paul S. Price
Ebert et al (see Exposure Factors Handbook for the reference.)

Paul S. Price
Price, P., J. Sample, and R. Strieter. 1992 Determination of less-than-lifetime exposures to point source emissions. Risk Anal. 12(3):367-382.

Paul S. Price
Price, P.S., C.L. Curry, P.E. Goodrum, M.N. Gray, J.I. McCrodden, N.W. Harrington, H. Carlson-Lynch, and R. E. Keenan. 1996. Monte Carlo modeling of time-dependent exposures using a Microexposure event approach. Risk Anal. 16(3): 339-348.

TECHNICAL BACKGROUND DOCUMENT:
RISK CHARACTERIZATION

RESPONSE TO CHARGE:

1. Do you agree with the risk characterization based upon your review of the exposure evaluation and the risk assessment in the Technical support Document?

Robert J. Fares
This reviewer agrees with the risk characterization based on the review of the exposure evaluation and the risk assessment in the Technical Background Document. However, it is this reviewers understanding that some of the results in Sections 7.1.3 through 7.2 of the Technical Background Document may change as a result of new data input.

Curtis C. Travis
Yes, I believe that the document provides a comprehensive assessment of the risks posed to farmers and their families by the application of sewage sludge on agricultural land.

Paul S. Price
It is difficult to agree with a document when its purpose is unclear. The document is a series of separate discussions on various aspects of risk characterization that no clear argument organization. I agreed with most of the points made.

2. The reviews will provide specific language to EPA on their characterization of the risk assessment, e.g., "high end", "bounding", "central tendency", etc.

Curtis C. Travis
I believe that the risk assessment performed represents a "high-end" exposure and individual risk. Not only is the farm family assumed to live on the farm, but also it consumes a large fraction of its diet from farm grown food, an unlikely event. It may be that a farm family consumes a high fraction of some diet item (like fruit or vegetables) from farm-produced food, but it is very unlikely that any farm family obtains large fractions of all diet items (fruit, vegetables, meat, milk, chicken, eggs, fish, etc.) from their farm. Thus, this exposure scenario represents a "high-end" exposure. In addition, all reasonable exposure pathways are evaluated and high-end exposure parameters are used in the evaluation. Thus, I believe this risk assessment represents a "high-end" assessment of the risk of agricultural application of sewage sledge.

Paul S. Price
See discussion under general comments

SPECIFIC COMMENTS

Curtis C. Travis
Page 1; Paragraph 3
I am in agreement that the current risk assessment represents an assessment of the risk to the "high-end" of the exposed population since it is for the farm family living on a farm (and obtaining a large percentage of their diet from their own farm products), where sewage sledge is land applied as a fertilizer or soil amendment. I am also in agreement that establishing numerical standards to protect this "high-end" exposed farm population from exposure to dioxins in sewage sledge will be protective of the general population.

Curtis C. Travis
Page 2; Paragraph 4
The text says, "…the farmer never rotates the pasture to grow row crops where presumably, tilling of sewage sludge in the soil would occur to mitigate dioxin volatilization transport to the row crops." The point of this sentence is not clear. Is it that the rotation to grow row crops in pastureland would result in higher row crop concentrations because of higher application rates to pasture?

The exact percentages devoted to crop production and animals raising (pasture land) are unimportant as long as the farm produces sufficient crops and animal products to feed to farm family (using the consumption rates from the document).

Curtis C. Travis
Page 3; Paragraph 2
There is no doubt that the scenario presented is a "high-end" exposure. Not only is the farm family assumed to live on the farm, but also it consumes a large fraction of its diet from farm grown food, an unlikely event. It may be that a farm family consumes a high fraction of some diet item (like fruit or vegetables) from farm-produced food, but it is very unlikely that any farm family obtains large fractions of all diet items (fruit, vegetables, meet, milk, chicken, eggs, fish, etc.) from their farm. Thus, this exposure scenario represents a "high-end" exposure.

Curtis C. Travis
Page 3; Paragraph 5
The text says, "…high end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk." It is not clear that a farm family living of a farm and obtaining a large fraction of their entire food intake from farm-produced food is a scenario that actually occurs. Thus, the risk computed as "high-end" in this assessment may be above that actually experienced by any real family living on a farm using sewage sludge. However, since the actual diet of a farm family living on such a farm is unknown, the exposure scenarios and assumption used in the present assessment are reasonable and appropriate.

Curtis C. Travis
Page 4; Bullet 3
The text says, "Fractions of home produced beef, milk, eggs, and poultry …". While these may be central tendency values, it is very unlikely that any farm family will actually consume farm-produced food as a major part of the entire diet. Thus, this assumption is a high-end assumption.

Curtis C. Travis
Page 4, Bullet Third from Bottom
The text says, "Concentration of dioxin in aqueous phase of maternal milk- literature value." From this assumption, it is not clear if the document is using background dioxin concentrations in maternal milk or calculated concentrations based on intake of dioxin in farm food. The first bullet on page 5 indicates the document is calculating the concentration of dioxin in maternal milk. Why then is a literature value for the concentration of dioxin in aqueous phase maternal milk used in this document?

Curtis C. Travis
Page 6; Bullet 3
The text says, "It may also be acceptable to characterize this risk assessment as the "high-end" of the "high-end". " I agree with this statement. Because of the very conservative assumptions regarding dietary exposure (concurrent exposure to farm-produced meat, milk, fruit, vegetables and home-caught fish) for the farm family, I believe that this is a high-end of the high-end assessment.

ESTIMATE OF POPULATION EXPOSED TO DIOXINS FROM THE LAND APPLICATION OF SEWAGE SLUDGE AND CORRESPONDING NUMBER OF ANNUAL CANCER CASES FROM THIS EXPOSURE

RESPONSE TO CHARGE:

1. Are the assumptions that are stated in the estimates reasonable?

Robert J. Fares
The assumptions stated in the estimates appear to be reasonable.

Curtis C. Travis
I believe that both the estimated size of the exposed population and the number of annual cancer cases are over estimates. U.S. Census data indicate that within the U.S. population of 2.8 x 10+8 individuals, about 2 percent lives on farms. The document assumes that the entire 2% raise their own crops and animals, and consume a significant portion of their annual diet from their farms. This is highly unlikely.

There are about 1.9 million farms in the United States and 1.56 percent of the U.S. population lived on farms in 1990 (U.S. census data). The 1997 U.S. farm census data show that of the 1.9 million farms, 800,000 produce beef cattle, 116,000 produced milk, and 106,00 have orchards and only 53,000 harvested vegetables (reference given below). These data indicate that concurrent exposure by a farm family to farm-produced meat, milk, fruit, vegetables and home-caught fish is unlikely to occur. An assumption of concurrent exposure to these food items is appropriate in estimating high-end individual exposure. However, in estimating population exposure and risk, this assumption overestimates the exposed population and the number of annual cancer cases.

Paul S. Price
I agree with the finding of this assessment it to present a quick argument that the risks from the land disposal are very small. However, the current use of conceptual site layout presents a conceptual problem for estimates of population risks. It is difficult to talk about the number of individual who have exposures similar to those described in the conceptual site layout. In that sense, the number of individual exposed would be zero. The real question is what is the number of individual who consume "home raised" beef that has been pastured or fed silage from land treated with sludge. This could be better estimated.

2. Are the calculations for the estimated population modeled and the annual cancer cases from the population performed correctly?

Robert J. Fares
The calculations for the estimated population and annual cancer cases from the population were performed correctly.

Curtis C. Travis
The calculations of estimated size of the exposed population and the number of annual cancer cases in this population appear to be performed correctly.

Paul S. Price
The assessment has a number of problems with its inputs.

Where did the value of 6x 10-6 come from? This should be documented citing the page/table from Document 1. In addition, EPA should indicate if it is driven by beef/dairy exposures.

The assessment is likely to be an overestimate of actual risks (see comments on beef consumption below).

I find it implausible that 2% of the US live on farms, raise beef, and consume the beef they raise. Farmers that do not raise beef should not be included in the calculation since their risks are much less than cattle ranchers.

I had the following suggestions for the calculations:
I would estimate the population size by taking the total number of farms estimated to take biosolids in a year and raise either beef or dairy cattle, and the demographics of farms (older adults, few children, etc) to estimate the size of the population affected.

The annual risks should be estimated based on a division by the duration of exposure not 70 years (Price et al., 1992).

The size of the population should be estimated by determining the number of farmers who will move to or reside at a farm over the 40-year application time. This can be estimated by taking the number of farms, multiplying it by 40 years and dividing by the average duration for adults.

SPECIFIC COMMENTS

Curtis C. Travis
Page 1; Bullet 2
The text says, "Two percent are the "high-end" modeled population that live on farms, raise their own crops and animals, and consume a significant portion of their annual diet from their farms," I believe that this is an unrealistically high estimate. It may be that about two percent of the U.S. population lives on farms, but it is vary unlikely that they consume a significant portion of their annual diet from their farms. There are about 2 million farms in the United States and 1.56 percent of the U.S. population lived on farms in 1990 (U.S. census data). The percentage is undoubtedly less now. However, only about 100,000 of these farms are licensed to produce milk. Thus, the assumption that all of these farms produce milk for their own consumption is not realistic. The probability that these same 100,000 farms also produce beef for home consumption is unlikely.

1997 U.S. farm census data show 1.9 million farms, 800,000 produce beef cattle, 116,000 produced milk, 106,00 have land in orchards and only 53,000 harvested vegetables. (http://www.nass.usda.gov/census/census97/highlights/usasum/us.txt)

Curtis C. Travis
Page 1; Bullet 3
This is an over-estimate of the number of individuals in the high-end population.

Curtis C. Travis
Page 1; Bullet 4
This assumption seems reasonable.

Curtis C. Travis
Page 1; Bullet 6
What does the term "TSD" stand for?

APPENDIX A

Robert J. Fares

APPENDIX B

Paul S. Price

APPENDIX C

Curtis C. Travis